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Exploring the Relationship Between Schema Modes, Cognitive Fusion and Eating Disorders

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Contents

Chapter One

A Systematic Review of the Evidence Base for Schema Therapy

Written for the journal of Cognitive Behaviour Therapy (see appendix K for author guidelines)

Abstract

Aim: Schema therapy is becoming an increasingly popular psychological model for working with individuals who have a variety of mental health and personality difficulties. The aim of this review is to look at the current evidence base for schema therapy and highlight directions for further research.

Method: A systematic search of the literature was conducted up until January 2011. All studies that had clinically tested the efficacy of schema therapy as described by Jeffrey Young (Young, 1994; Young *et al.*, 2003) were considered. These studies underwent detailed quality assessments based on Scottish Intercollegiate Guidelines Network (SIGN-50) culminating in twelve studies being included in the review.

Results: The culminative message (both from the popularity of this model and the medium to large effect sizes) is of a theory which has already demonstrated clinically effective outcomes in a small number of studies and which would benefit from ongoing research and development with complex client groups.

Recommendations: It is imperative that psychological practice be guided by high quality research that demonstrates efficacious, evidence based interventions. It is therefore recommended that researchers and clinicians working with schema therapy seek to build on these positive outcomes and further demonstrate the clinical effectiveness of this model through ongoing research.

Introduction

Within public healthcare organisations, mental health professionals are continually striving to provide the best interventions and treatments available. Until recently there was a dearth of research which supported the effectiveness of psychological therapies for personality disorders (Fonagy & Bateman, 2006). These client groups were considered 'untreatable' by many due to the lack of treatment models available with adequate sophistication and depth to address the needs of these more complex client groups (Young, Klosko & Weishaar, 2003). With new psychological theories constantly evolving it is essential to ensure that clinical practice keeps pace with research evidence. In such dynamic environments, systematic reviews are starting to play an increasingly important role in assessing the existing evidence for psychological interventions (SIGN, 2008).

The aim of this review is to collate the current evidence base for one of the more recent psychological interventions; schema therapy (Young, 1994, Young *et al*., 2003). Schema therapy (ST) was developed by Jeffery Young in the 1980's with the goal of improving interventions for individuals who had personality disorders and more complex, chronic, and characterological difficulties. Such individuals are often considered 'difficult to treat' using traditional cognitive therapy, and are frequently described as 'treatment failures' (Young *et al.,* 2003). From extensive clinical experience Young identified that such individuals appeared to benefit from some adaptations to traditional cognitive therapy. Overtime these adaptations evolved into ST; a broad integrative model which overlaps with other models of psychopathology including Cognitive Behavioural Therapy and psychodynamic models (Young *et al*., 2003).

Over recent years this model has become increasingly popular with clinicians and academics who have started to test both the theoretical assumptions and clinical

effectiveness of this model. However, due to the recency of both the model and research in this area, no other review has been conducted in this field to our knowledge.

What is Schema Therapy?

There are four main concepts that are central to ST; these are *Early Maladaptive Schemas, Coping Styles, Schema Domains* and *Schema Modes* (Young *et al.*, 2003). Early Maladaptive Schemas (EMS) are at the heart of model. Currently there are 18 EMS which are described as, '*extremely stable and enduring themes, comprised of memories, emotions, cognitions, and bodily sensations regarding oneself and one's relationship with others, that develop during childhood and are elaborated on throughout the individual's lifetime, and that are dysfunctional to a significant degree'* (Young *et al.* 2003, p.7). Young states that schemas are present in every human being but that they are manifested in a more rigid and extreme way in cases of psychopathology.

Early Maladaptive Schemas commonly develop in children who live within an environment which fails to meet their core emotional needs, or where they experience repeated episodes of abuse, neglect, hostility and criticism (Young *et al.*, 2003). Depending on the child's early environment the development of schemas can be grouped into 5 domains: *disconnection and rejection, impaired autonomy and performance, impaired limits, other directness* and *over vigilance and inhibition*. Each domain represents an important component of a child's core needs, for example, schemas in the *disconnection and rejection* domain typically originate in detached, cold, rejecting, withholding, lonely, explosive, unpredictable, or abusive families (Young *et al*., 2003).

Coping styles refer to the ways a child adapts to these environments and experiences. There are three main coping strategies used; overcompensation (fighting the schema and acting as though the opposite were true), surrendering (or giving in to the schema) and

avoidance (trying to avoid schema activation) (Young *et al.*, 2003). Although these coping styles initially develop to help a child survive toxic environments, over time and in different environments such strategies can serve to maintain the dysfunctional schemas and cease to serve an adaptive function for the individual (Young *et al.*, 2003).

Schema modes are the most recent addition to the ST model. Modes reflect the moment-to-moment emotional and behavioural state of a person at a given time. Modes comprise of clusters of schemas, for example, *defectiveness* (the belief that one is flawed or defective) and *emotional deprivation* (the belief that you will never be understood and that your needs will never be met by others) are both part of the *lonely child mode*. ST and schema mode therapy do not reflect two separate entities, rather schema mode work is seen as an advanced component of ST which is particularly beneficial when working with individuals who have borderline personality disorder or other complex presentations. Such individuals often present with a number of schemas being simultaneously activated, which can make individual schema work more complex (Young *et al.*, 2003). By allowing therapists to work with groups of schemas simultaneously, schema mode therapy can simplify therapeutic interventions for some individuals.

The Goal of Schema Therapy

Young *et al.,* (2003) explain that a healthy person can adaptively meet their own core needs through self-care and close adaptive relationships with others. The goal of ST is to help those who are currently unable to do this. This may involve identifying and reducing maladaptive coping behaviours which function to perpetuate schemas and reduce the likelihood of schema change, whilst developing healthier, more adaptive alternatives, and healing unhelpful schemas. This can be a long process which requires the individual to

confront and modify schemas that may have previously served a protective and adaptive function.

In schema therapy the therapeutic relationship is seen as the foundation for these changes to occur. As early maladaptive schemas and modes arise when core needs are not met, schema therapists aim to identify and meet these previously unmet needs in a limited way within the therapy relationship using a variety of techniques including empathic confrontation, experiential, cognitive and behavioral strategies. This may then progress to mobilising other supportive relationships. By helping the individual identify missed experiences or unmet needs in early childhood and providing opportunities to address these within a therapeutic relationship, schema therapy serves as an antidote to the early damaging experiences that led to the formation of maladaptive schemas and modes. In ST this is referred to as 'limited reparenting' (Young *et al.,* 2003).

Why conduct this review?

Over the last 20 years, ST has evolved into a model which is both simple to understand whilst also deep and complex in nature. The combination of these factors has resulted in it being a popular model with clinicians and researchers. The aim of this systematic review is to identify and consolidate the current clinical evidence base for ST and suggest areas in need of future development.

Method

Review objective

To review the treatment evidence for schema therapy as described by Jeffrey Young (Young, 1994; Young *et al*., 2003).

Inclusion and Exclusion Criteria

- ***Participants*.** The only fixed exclusion criteria was age. No study with participants under the age of 18 was included in this review.

- ***Psychopathology*.** To ensure this review represents a broad range of individuals, all forms of intervention (for example, group and individual formats) and psychopathology were considered. Due to the high prevalence of co-morbidity of mental health conditions it was considered clinically useful to include studies with participants who may have more than one mental health diagnosis.

- ***Setting.*** The aim of this review is to evaluate ST in a broad range of mental health settings to optimise its clinical utility. Therefore both inpatient and out patient settings were considered.

- ***Interventions.*** Due to the limited number of outcome studies in this area all studies that applied ST to individuals with a mental health condition were considered. Although it is anticipated that number of sessions will vary, only studies that evaluated the efficacy of a ST intervention and exceeded ten sessions were included in the review. This is due to ST aiming to achieve deep schema change which is unlikely to occur in very short interventions.

- **Outcomes.** As ST may have a variety of different outcomes depending on the individual's unique needs all outcomes were considered.

- **Language.** Only English language studies were included due to lack of translation resources.

- **Study Design.** Ideally, systematic reviews only consider evidence from high quality randomised controlled trials (RCT's). However, there are many who feel that this may not be the best way of evaluating the true value of psychological treatments for personality disorders (Emmelkamp & Vedel, 2009). This is due to the inherent problems in running research with such complex client groups. Additionally, RCT's do not tell us much about implementing psychological treatments in real public health service settings. This is due to their strict guidelines and inclusion criteria which are often unrepresentative of routine clinical practice. As research into psychological therapies is ultimately about informing clinical practise this review will therefore include RCT's, controlled trials (CT) and uncontrolled trials (UT). Single case studies or studies with less than five participants will be excluded from the review owing to the higher potential for bias in these study designs. Finally, economic evaluations and studies using duplicate data will not be included.

Search Strategy

The following search terms were used in this study; ‘schema therapy’ or ‘schema focused therapy’. However, for the purposes of this study, it will be referred to as ‘schema therapy’ which is now the most commonly used description.

The following electronic databases were searched until the 10th January 2011.

• MEDLINE (from 1950);

• EMBASE (from 1980);

• CINAHL (from 1982);

• the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2009, issue 3);

• PsycINFO (from 1872);

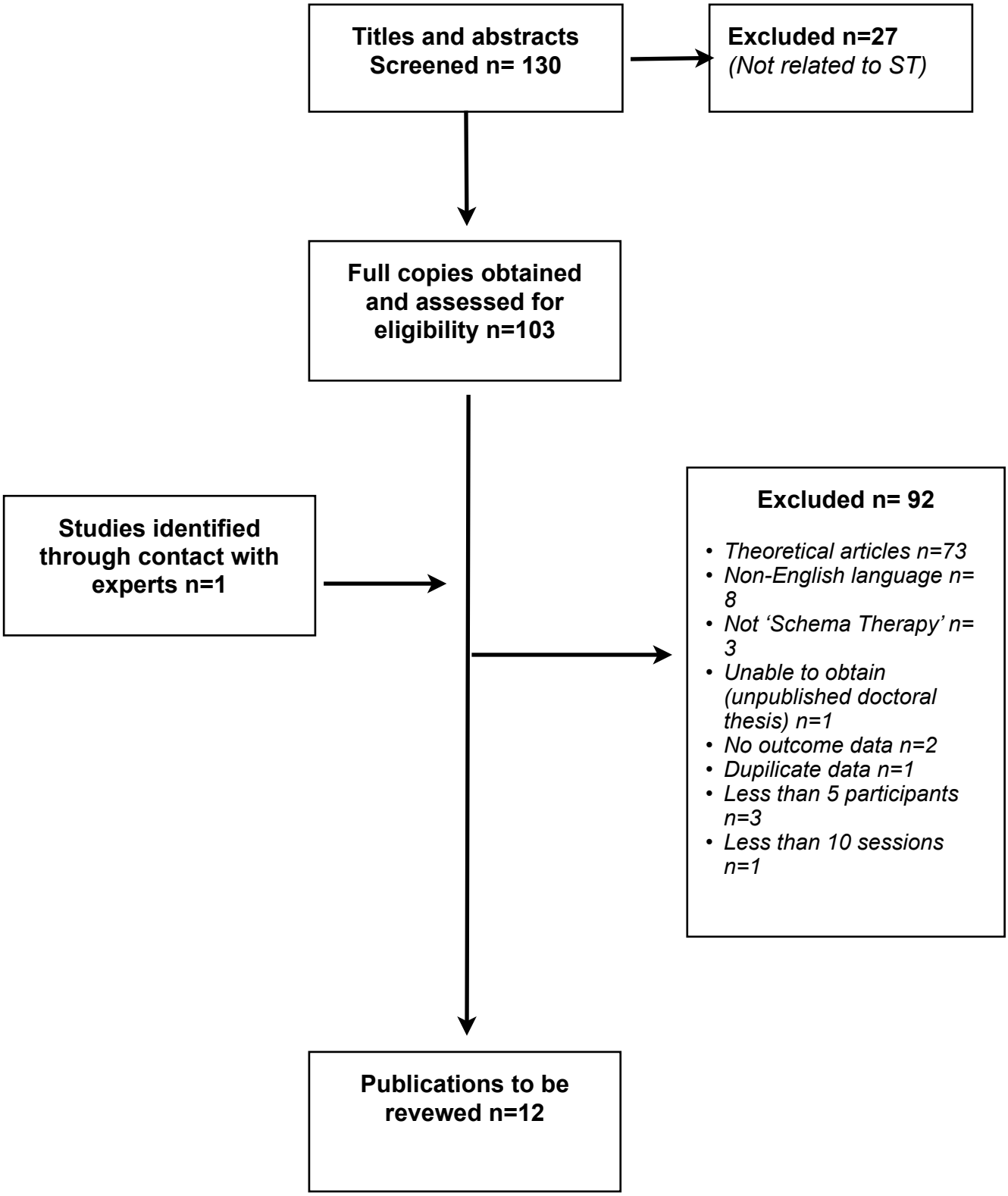
Searching other resources

The reference lists of included and excluded studies were searched for additional studies and prominent researchers were contacted to enquire about other sources of information including ongoing research or unpublished data. Finally, two prominent ST websites (the International Society for Schema Therapy, http://www.isst-online.com/ and Schema Therapy website, http://www.schematherapy.com) were also searched.

Study selection

All titles and abstracts were initially screened and irrelevant studies or purely theoretical studies were excluded. The full text of all remaining studies were obtained and read. Studies utilising data previously reported were removed to prevent duplication. A flowchart of the selection process can be seen in Figure 1.

Figure 1. Flow chart of study selection process



Results

Following this selection procedure twelve studies met all the study requirements. These can be found in Table 1. In total four of the studies were considered to be assessing the effectiveness of ST in the treatment of BPD (Farrell, Shaw & Webber, 2009; Giesen-Bloo van Dyck, Spinhoven, van Tilburg, Dirksen, van Asselt, *et al.*, 2006; Nadort, Arntz, Smit, Giesen-Bloo, Eikelenboom & Spinhoven, 2009; Nordahl & Nysaeter, 2005), one focused on the effectiveness of ST techniques in the treatment of childhood memories (Weertman & Arntz, 2007), two targeted substance misuse and concurrent personality disorders (Ball, 2007; Ball, Cobb-Richardson, Connolly, Bujosa & O'neall, 2005), one looked at ST for PTSD (Cockram, Drummond & Lee (2010), one evaluated group schema therapy in an eating disorder population (Simpson, Morrow, van Vreeswijk & Reid, 2010), and three focused on individuals with agoraphobia and cluster C personality disorders (Gude & Hoffart, 2008; Gude, Monsen & Hoffart, 2001; Hoffart & Sexton, 2002).

Table 1. Summary of included studies.

Study Reference	Aim	Design	Intervention	Outcome Measures	Conclusions	Effect Sizes
Ball, S. A. (2007). Comparing individual therapies for personality disordered opioid dependent patients.	To compare Dual Focus Schema Therapy (DFST) to a 12 Step Facilitation Therapy (12FT) in 30 partipants (15 male and 15 female) with a diagnosed personality disorder and concurrent substance misuse.	RCT	Six months of either DFST or 12FT.	Substance use time line calender; Addiction Severity Index; Brief Symptom Index; Multiple Affect Adjective Checklist-Revised; Working Aliiance Index.	Both groups demonstrated a reduction in substance misuse, this was more rapid in the DFST condition. Participants reported a stronger therapeutic alliance in the DFST condition. Reduction in dysphoric affect did not occure in the DFST but did in the 12FT group.	Unable to compute
B**all et al., (2005).** Substance abuse and personality disorders in homeless drop-in center clients: Symptom severity and psychotherapy retention in a randomized clinical trial.	To compare Dual Focus Schema Therapy (DFST) to standard group substance abuse counselling (SAC) in 52 male homeless clients with a diagnosed personality disorder and concurrent substance misuse.	RCT	24 weeks of either DFST or SAC.	Due to low retention of participants so was only able to provide outcome data on utilisation of therapy.	Greater utilisation of DFST overall however, individuals with more severe personality disorders utilised SAC more than DFST.	Unable to compute
Cockram, Drummond & Lee (2010). Role and treatment of early maladaptive schemas in Vietnam veterans with PTSD. (Study Two)	To compare SchemaTherapy (ST) with traditional CBT (TCBT) for the treatment of PTSD in war veterans. TCBT was delivered to 127 individuals between 1996 and 2002. ST was delivered to 54 veterans between 2007 and 2008.	CT	190hrs of either ST or TCBT.	PTSD Checklist Military; Young Schema Questionnaire -L3; Hospital Anxiety and Deperession Scale.	PTSD symptoms, anxiety, depression and EMS decreased significantly following ST. When compared to TCBT, the ST group showed significantly greater reductions in PTSD and anxiety symptoms.	Between intake and follow-up, effect sizes were medium to large in the ST group (Cohen's d between 0.61 and 0.82) and small to medium in the CBT comparison group (between 0.3 and 0.53).
Farrell, Shaw Webber, (2009). A schema-focused approach to group psychotherapy for outpatients with borderline personality disorder: a randomised controlled trial.	This study tests the effectiveness of adding an eight month, thirty session schema focused therapy (ST) group to treatment as usual (TAU) for 32 women with a diagnosis of borderline personality disorder (BPD).	RCT	Either eight months (30 sessions) of group ST and TAU or just TAU.	Borderline Syndrome Index; SCL-90R, Diagnostic Interview for Borderline Personality Disorders - Revised; Global Assessment of Functioning Scale. These were administered pre-treatment, post-treatment, and 6-month follow up.	At the end of the treatment 94% of ST + TAU group no longer met the criterion for BPD, whilst only 16% of TAU no longer met the criterion. Significantly lower scores on BSI, DIB-R and SCL-90R and higher scores on the GAF. These effects were maintained at six-month follow up.	At follow up, effect sizes using pooled standard deviations were all large in the ST group (between 4.45 and1.17) and all small in treatment as usual (between -. 14 and 0.35).

Study Reference	Aim	Design	Intervention	Outcome Measures	Conclusions	Effect Sizes
Giesen-Bloo et al, (2006) Outpatient Psychotherapy for Borderline Personality Disorder,	To compare the effectiveness of schema therapy (ST) and transference focused therapy (TFT) in 88 patients with a diagnosed borderline personality disorder (BPD) index score above 20.	RCT	Two sessions per week for three years of either ST or TFT.	Borderline Personality Disorder Severity Index score (4th version); Quality of life; general psychopathological dysfunction; and measures of schema therapy/ transference focused psychotherapy personality concepts.	Three years of schema therapy or transference focused psychotherapy reduced BPD specific (and general) psychopathologic dysfunction; improved quality of life and increased model specific concepts. The BPDSI-IV demonstrated ST to be more effective than TFT on the following sub scales; abandonment fears (p=.04), relationships (p=.03); identity disturbance (p=.02), impulsivity (p=.03, para-suicidal behaviour (p=.04) and dissociative and paranoid ideation (p=.02). No significant differences were found on the other sub scales however there were significantly stronger linear trends for ST increasing quality of life.	With respect to the study's main outcome measures,1-year of ST resulted in Cohen's d ranging between 0.43-1.03 and inTFP between 0.09- 0.99.
Gude & Hoffart, (2008). Change in interpersonal problems after cognitive agoraphobia and schema-focused therapy versus psychodynamic treatment as usual of inpatients with agoraphobia and cluster C personality disorders.	Will ST increase interpersonal functioning more than TAU in patients with panic disorder, agoraphobia and co-occurring cluster C traits?	CT	12 weeks of either group TAU or group ST.	IIP, Symptom Check List -90; Mobility Index for Agoraphobia. These were administered at pre-treatment, discharge and follow-up.	Patients in the ST group showed greater improvement in interpersonal function than treatment as usual.	Effect sizes from pre-treatment to follow-up on the IIP and SCL-90 phobic anxiety sub-dimension were large in the group of those having completed ST (0.88 and 1.82) whereas the TAU group exhibited low to moderate effect sizes (0.55 and 0.01).
Gude, T., Monsen, J. T., & Hoffart, A. (2001) Schemas, affect consciousness, and Cluster C personality pathology: a prospective one-year follow-up study of patients in a schema-focused short-term treatment program.	To determine if a low level of affect consciouness will be related to a high level of cluster C pathology at pretreatment; if change in cluster C pathology is influenced by change in affect consciousness; affect consciousness will any change during schema focused phase.	One group (pre-post design)	11 week inpatient group; 5 weeks cognitive treatment of panic/ agoraphobia and 6 weeks ST.	The Affect consciousness Interview; Mobility Inventory and the Structured Clinical Interview for DSM IV.	Pretreatment level of affect consciousness did not correlate with Cluster C personality indexes but the Avoidant index did at post-treatment. Affect consciousness changed during the ST phase but not the CT phase. These results indicate that ST may increase affect consciousness more than CT.	The overall change between pre-treatment and follow-up on the measures of personality change ranged between 0.20 and 0.5.
Hoffart, Sexton, (2002) The role of optmism in the process of schema-focused cognitive therapy of personality problems.	To examine the role of optimism in the process of ST in 35 patients with panic disorder and or agoraphobia and DSM-IV Cluster C personality traits.	One group (pre-post design)	11 week inpatient group; 5 weeks cognitive treatment of panic/ agoraphobia and 6 weeks ST.	The Affect consciousness Interview; Mobility Inventory, the Structured Clinical Interview for DSM IV, Panic Rating Scale, the State-Trait Anxiety Inventory, Schema Questionnaire and the Inventory of Interpersonal Problems.	Positive association between optimism and schema processes and between EMS and level of distress, empathy, insight and therapists optimism.	Effect sizes from pre-treatment to follow-up on the MI-AAL was 0.52, the STAI was 0.32 and the Personality Disorder cluster C index was 0.39.

Study Reference	Aim	Design	Intervention	Outcome Measures	Conclusions	Effect Sizes
Nadort et al., (2009) Implementation of outpatient schema therapy for borderline personality disorder with versus without crisis support by the therapist outside office hours: A randomised controlled trial.	Question 1. To evaluate the success of implementing outpatient schema focused therapy for 62 individuals with a diagnosis of BPD and to determine the added value of therapist telephone availability outside office hours in case of crisis.	RCT	Two 45 min sessions per week for 18 months either with or without therapist crisis support.	Borderline Personality Disorder Severity Index score(fourth version); EuroQol, WHOQol, BPD-47, SCL-90	No additional effect of extra crisis support with telephone availability were found.	Significant effects at 1.5 years of ST for the whole group emerged for patients' reduction of BPDSI scores (d=1.55), reduction on the BPD-47 scores (d=0.80), SCL-90 scores (d=0.57) and theYoung Schema Questionnaire (d=0.69).
	Question 2. A second aim was to compare the outcomes of this study with the previous RCT conducted by Giesen-Bloo et al, 2006 to determine if similar outcomes would be found in regular practice.	CT	**Nadort et al's study**: two 45 min sessions per week for 18 months **Giesen-Bloo et al's** study: Two sessions per week for three years of either ST or TFT.	As above.	ST can be successfully implemented in regular mental healthcare. Treatment results and drop out were comparable to a previous clinical trial.	In the RCT (Giesen-Bloo et al., 2006) a pre- to post-treatment effect size difference of d =1.24 was found on the BPDSI. In the present study the pre–post-difference was d=1.55.
Nordahl & Nysaeter (2005) Schema therapy for patients with borderline personality disorder: a single case series.	To test the effectiveness of ST for six female patients with BPD in a single case series design.	Case series design	Between 18 and 36 months of weekly ST sessions.	The symptom checklist 90, revised, Beck depression inventory, Beck anxiety inventory, inventory of interpersonal problems, and the Young schema questionnaire.	From baseline to follow up improvement was clinically meaningful for five of the six patients. Three of the six patients did not meet the criteria for BPD by the end of therapy.	Cohen's d for the group of 6 patients as a whole showed that the pre-treatment to follow-up effects were large, with effect size ranging from 1.8 to 2.9.
Simpson, Morrow, Van VreeswijK, Reid, (2010) Group schema therapy for eating disorders: A pilot study.	To evaluate the effectiveness of group schema therapy for 8 individuals with a diagnosed eating disorder and co-morbid Axis I and II conditions.	Pre-post test case series design	20 group schema therapy sessions	EDE-Q, YSI-L2, HADS, EQ5-D and the Experience of shame scale.	Results indicated that 4 of the 6 completers had clinically sig improvement in eating. By follow up all completers had achieved over 60% improvement in schema severity.	Cohen's d showed that the pre-treatment to follow-up effects were all medium or large except on the measure of depression. The effect sizes ranged from 0.91-1.70.
Weertman & Arntz (2007) Effectiveness of treatment of childhood memories in cognitive therapy for personality disorders: A controlled study contrasting methods focusing on the present and methods focusing on childhood memories.	To test the hypothesis that treatment of childhood memories is an effective way to change peronality disorder related schemas and psychopathology in personality disorders in a sample of 21 participant's.	Cross over design	61 weekly ST sessions with 3 follow up assessments at 3, 6, and 12 months.	Rosenberg Self-Esteem-Scale, 90-item Symptom Checklist, Dutch Personality Questionnaire, Schema Questionnaire, Personality Disorder Belief Questionnaire; Miskimins self-goal-other discrepancy scale.	ST for personality disorder was associated with good overall improvements that were maintained. Given the absence of improvement during the exploration period, these effect sizes could not be attributed to attention effects. Experience of therapist in ST for personality disorder was related to better outcomes.	The effects of total treatment at post test, 3, 6, and 12 month follow up were large (d=0.97 - 1.97).

Quality Assessment

In order to differentiate between strong and weak evidence, quality assessments were carried out on all studies. To assist with these assessments the Scottish Intercollegiate Guidelines Network were used (SIGN 50, see appendix L). These checklists provided a framework to rate the methodological quality of each study. Based on these ratings each study was given one of the following overall quality ratings;

- 'A' was awarded to high quality randomised controlled trails which met all or most of the quality criteria and when not fulfilled the conclusions in the study were deemed very unlikely to alter.

- 'B' was awarded to randomised controlled trials and controlled trials which met most of the quality criteria and when the conclusions in the study were deemed unlikely to alter.

- 'C' was awarded to randomised controlled trial or controlled trials when few or none of the quality criteria had been fulfilled and the conclusions of the study were deemed likely or very likely to alter.

- 'D' was awarded to single group designs and uncontrolled studies.

To try and minimise bias in ratings, two studies were rated again by an independent rater and compared to the existing assessment. No differences were found between the researcher's assessment and the independent researcher's assessment on either study. Table 2 summarises the quality criteria ratings for this study.

Table 2. Quality assessment criteria based on SIGN-50 guidelines.

	Clarity of Question	Control condition used?	Treatment and control run simultaneously?	Similar control condition in relation to intensity, duration etc?	Randomisation used?	Similarity of groups at start	Treatment Integrity assessed?	Outcome measures?	Measurement of schema change?	Retention	Intention to treat analysis	Design	Follow up?	Quality rating
Ball, 2007	Well covered	Yes (12FT)	yes	Unknown - poor description	Yes but lacks description	Unknown	yes	Adequate	No	Poor	not reported	RCT	No	**C**
Ball et al., 2005	well covered	Yes (SAC)	yes	Poor	Yes but lacks description	Unknown	yes	Adequate	No	Very poor	No	RCT	No	**C**
Cockram et al., 2010	Well covered	TAU	No	well covered	No	Unknown	Unknown	Well covered	Only in SFT	100% in SFT unknown for comparison condition	No	CT	3 months	**B**
Farrell et al., 2009	Well covered	TAU	Yes	Poor	Random number table	Well covered	yes	Well covered	No	100% in SFT, 75% in TAU	No	RCT	6 months	**B**
Giesen-Bloo et al., 2006	Well covered	TFT	Yes	Yes	Adaptive biased Urn procedure	Well covered	yes	Well covered	No	73% SFT, 49% of TFT	Yes	RCT	Not officially but study was over 3 years	**A**
Gude and Hoffart, 2008	Well covered	TAU	No	Poor	no	well covered	Unknown	Well covered	No	72% TAU 100% SFT	Not reported	CT	12 months	**C**
Gude, Monsen & Hoffart, 2001	Adequate	No	n/a	n/a	n/a	n/a	Unknown	well covered	No	Good	not reported	UT	12-15 month	**D**
Hoffart & Sexton	Well covered	No	n/a	n/a	n/a	n/a	yes	Well covered	Yes	78%	no	UT	12 months	**D**
Nadort et al., 2009 *(Question 1: Telephone support)*	Well covered	Yes, No telephone support	Yes	Well covered	Stratified randomisation	well covered	Yes	Well covered	Yes	79%	Yes	RCT	No	**B**
(Question 2: were the results comparable to Giesen-Bloo et al., 2006.)	Well covered	Data from Giesen-Bloo et al's, study	No	Some differences	No	Some differences	Yes	Well covered	Yes	Nadort et al; 79% Giesen Bloo et al; 86%	Yes in both	CT	No	**C**
Nordahl & Nysaeter (2005)	Well covered	No	n/a	n/a	n/a	n/a	yes	Well covered	Yes	Good	n/a	UT	12 months	**D**
Simpson et al., 2010	Well covered	No	n/a	n/a	n/a	n/a	yes	Well covered	Yes	80%	n/a	UT	6 months	**D**
Weertman & Arntz (2007)	Well covered	No	n/a	n/a	n/a	n/a	yes	Well covered	Yes	100%	n/a	UT	12 months	**D**

Discussion

Schema therapy for BPD

In total, four studies looked at the effectiveness of ST in treating Borderline Personality Disorder (BPD). Of these, one compared treatment as usual (TAU) to TAU with group ST (Farrell *et al.,* 2009), another compared ST to Transference Focused Therapy (TFT) (Giesen-Bloo *et al.*, 2006), another compared ST with therapist telephone support to ST without therapist telephone support in a health service setting (Nadort *et al.*, 2009) and the other looked at ST for BPD in a case series design (Nordahl & Nysaeter, 2005).

Overall, of the four studies reviewed the most compelling evidence for the effectiveness of ST in treating BPD comes from Giesen-Bloo *et al's.*, (2006) study. This study directly compared the effectiveness of ST to TFT in 88 partcipants with a diagnosis of BPD. The rigorous assessment procedures, regular quality checks, standardised outcome measures and randomisation are particular strengths of this research. The main outcomes of this study were reductions in general and BPD specific psychopathological dysfunction, increased quality of life and significant improvements on BPDSI-IV subscales in the ST group compated to the TFT group (see table 1 for details). Overall the study's main outcome measures resulted in medium to large effects in the ST group (between 0.43-1.03) as compared to small to large effects (0.09-0.99) in the TFT group.

As well as these strengths, this study also benefits from the inclusion of a highly suitable control condition. TFT had previously demonstrated efficacy in reducing BPD symptoms in a randomised controlled trial (Clarkin, Levy, Lenzenweger & Kernberg, 2007). It also shares some characteristics with ST. For example, both aim to change personality

structure, reduce self destructive behaviours and increase quality of life (Giesen-Bloo *et al.*, 2006). Finally, both therapies can be offered in equal frequency and duration making it highly unlikely that the positive ST outcomes displayed could be attributed to other factors. TFT was therefore a good choice as a control group for the Giesen-Bloo *et al's* (2006) study.

One consideration when attempting to generalise these findings to other settings is the intensity and duration of the intervention. Athough personality disorders typically require greater intensity and duration of therapeutic input, planning sessions twice a week for up to three years maybe beyond the resources of some healthcare organisations.

The study by Nadort *et al.,* (2009) was set up as an 'implementation study' to determine whether the results found in Giesen-Bloo *et al*'s (2006) randomised controlled trial could be replicated in a public health service outpatient setting. For this reason they did not use a different treatment control, rather results were directly compared with those of the Giessen-Bloo *et al's* (2006) study. After the intervention phase, results and drop out rates were comparable between the two studies. This suggests that ST could be successfully implemented in regular practice. This type of study is important as it attempts to demonstrate efficacy in real health settings (rather than the controlled conditions found in a RCT). As such these findings may be more generalisable to public healthcare organisations.

However, interpretation of these results may be limited to some extent by some inherent differences between comparison groups. At pre-treatment, the participants in the 'implementation study' displayed lower BPDSI scores, less medication use and higher reported quality of life (Nadort *et al.*, 2009). They were also recruited in different time frames. Therefore this group may have been somewhat less severe than those in the

earlier clinical trial by Giesen-Bloo *et al* (2006). Nevertheless, all participants did meet full criteria for BPD in both studies. Ideally, future research attempting to demonstrate efficacy in general practice should use a simultaneous active treatment control allowing randomisation to either ST or the control group. This design would better control for non-therapeutic factors that may influence the outcomes. However, practically this design might be difficult to achieve in regular clinical practice. Under such circumstances a well conducted quasi experimental design controlling for baseline differences may be more achieveable (Emmelkamp & Vedel, 2009).

Overall, the study by Nadort *et al*. (2009) provides additional clinically useful information which would not be easily obtainable within a pure RCT trial. One of the main aims of this research study was to determine the added benefit of out of hours therapist telephone support to the treatment outcomes. Telephone support has been one of the more controversial aspects of ST within some health care settings and potentially may deter therapists from using this model. Interestingly, this study suggested that there was no added benefit of telephone support. The implications of these findings may make ST more accessible and less onerous for therapists working in settings not set up to support this level of out of hours support.

The study by Nadort & Nysaeter (2005) used a case-series design and as such participants in this study acted as their own controls. Although small in size, the large effect sizes of the main outcome measures between pre-treatment and follow up were comparable to those in much larger studies. Additionally, the outcome measures were administered at regular intervals in a controlled way. These findings therefore contribute to the positive outcomes of ST.

The final study looking at ST for the treatment of BPD was conducted by Farrell *et al.,* (2009). This study appears to show the largest benefits in reducing BPD symptoms suggesting that 94% of participants attending a ST group (in addition to treatment as usual (TAU)) no longer met criteria for BPD at end of treatment. However, other factors could account for some of these benefits, making it difficult to generalise the findings of this as a stand-alone study. Firstly, the ST condition received greater frequency of therapeutic input, with an additional 90 minutes structured clinical contact per week which was specifically targeted towards reducing BPD symptoms. It is possible that the structured group environment with targeted content and additional time may account for some of the perceived differences rather than the ST component. As each treatment is likely to have its own structure it can be difficult to match one type of therapy with another. This is a more general difficulty when investigating psychological therapies. Ideally, in order to establish if ST is the primary change factor, future research should compare group ST to a control treatment that is as equally structured, targeted and intense as possible. Additionally, the group ST treatment was run by its developers (suggesting high treatment fidelity) so it remains to be seen how effective other therapists are in delivering this intervention.

Possible challenges to research in this area

Ideally, it is recommended that future research of similar quality to Giesen-Bloo *et al's* (2006) study is conducted, comparing ST to a suitable control treatment (such as TFT or Dialectical Behaviour Therapy (DBT), Linehan, Comtois, Murray, Brown, Gallop, Heard, *et al,* 2006). Such controlled comparisons are needed in order to enhance the evidence base for ST in general clinical practice. However, realistically it is acknowledged that there may be some difficulties doing this type of research within healthcare organisations with resource pressures. Clinicians working within healthcare organisations need to have managerial support for both their clinical time and resources. ST is still relatively new and

under-researched. Within the current economic climate it may be challenging to get managerial support for ST research within healthcare departments that might be under pressure to provide time limited evidenced based treatments. It might be helpful for clinicians seeking funding for such research to read the economic evaluation by van Asselt *et al.,* (2008). This evaluation looks at the overall costs of BPD and compares this with the treatment costs. Although it is beyond the scope of this evaluation to go into this paper in more depth, this evaluation appears to provides compelling evidence to suggest that ST, is a cost effective treatment when taking into account the wider costs associated with supporting clients with personality disorders both within healthcare organisations in addition to wider societal costs. Overall, these difficulties may explain the scarcity of research into ST.

Research recommendations

Despite these potential challenges, the research conducted to date suggests that ST displays mainly large effect sizes and positive outcomes in decreasing BPD symptoms. Although clinicians who work in this field may be under pressure to provide succinct, cost effective treatments, the complex nature of personality disorders means that at face-value, ST may initially appear an expensive intervention but may in reality be more cost effective than other treatments (van Asselt, Dirksen, Arntz, Giesen-Bloo, van Dyck, Spinhoven *et al,* (2008). Another way to make this therapy more accessible could be to look at group ST, rather than individual sessions. This is supported by Farrell *et al's* (2009) study which suggests that group processes may improve the effectiveness of ST whilst also reducing the length of treatment required.

Finally, although difficult to perfectly match psychological therapies in terms of intensity, duration, structure and treatment goals, future research should aim to use control

conditions which are as similar to ST as possible. If control conditions vary in terms of intensity, frequency, duration and goals it becomes difficult to determine if observed effects are due to the psychological treatment or differences in other factors such as design and methodology.

Schema Therapy for Personality Disorder

The study by Arntz & Weertman (2007) explored whether treatment of childhood memories is an effective way to change personality disorder related schemas and psychopathology. This study used a cross over design and therefore did not have a simultaneous active treatment control. Overall, ST was associated with good overall outcomes and large effect sizes. Interestingly this study also looked at the impact therapist experience had on outcomes. ST for BPD (and personality disorder in general) requires therapist training and supervision (Young *et al*., 2003). This study demonstrates the positive clinical impact of increased therapist experience on therapeutic outcomes. Such findings suggest that therapist experience may be an important influence on the outcomes of ST.

Schema Therapy for PTSD

The study by Cockram, Drummond & Lee (2010) aimed to determine if group ST would reduce PTSD symptoms in war veterans compared to a comparison CBT group that was previously run in the clinic. The main difference between the ST group and the CBT group was the content of six cognitive restructuring sessions. In the ST group, these six sessions focused exclusively on schema work and included trauma imagery which allowed reprocessing of childhood experiences. There was also reference to how early experiences could have made some individuals more vulnerable to PTSD which was absent in the CBT group. Overall, this study suggests the ST group had significantly better

outcomes than the CBT group in reducing PTSD symptoms and anxiety. There was no significant difference between the ST and CBT group in depressive symptoms.

This study benefits from having a control condition which was similar in content, structure and duration to the ST group. However, there are some methodological and statistical weaknesses which could be addressed in future research. In this study, the participants were recruited during different time frames which meant that randomisation was not possible. Additionally, it is possible that other changes in the clinic may have impacted on the outcomes; for example, treatment fidelity and therapist experience were not reported in this study.

A particular strength of this study was the measurement of schema change. As the primary aim of ST is to reduce the impact of early maladaptive schemas, more studies would benefit from formal assessment of schema change. Unfortunately as data was collected retrospectively the control CBT group had not completed a post intervention schema measure. As the content and structure of these groups had large amounts of overlap, it would be interesting to determine if the relatively small amount of schema change work in the ST group impacted upon early maladaptive schemas as compared to the control CBT group. This makes it impossible to determine if schemas reduced more in the ST than in the CBT group. However, the ST group demonstrated larger effect sizes than the CBT group on the other outcome measures suggesting ST was more effective in general.

Overall, this study provides an indication that further research in this area would be beneficial. As this study focused on a particular subset of PTSD sufferers, it would be interesting to look at interventions that target PTSD that has arisen from a greater variety of trauma experiences. It would also be beneficial to compare ST to other psychological interventions which have evidence in treating trauma such as Prolonged Exposure (Foa,

Hembree & Rothbaum, 2007), Cognitive Restructuring (Ellis & Harper, 1975) or Eye Movement Desensitisation and Reprocessing (Shapiro, 2001).

Schema therapy for agoraphobia and cluster C personality disorders

Three studies have investigated the evidence for applying group ST to inpatients with agoraphobia and cluster C personality disorders (Gude & Hoffart, 2008; Gude, Monsen & Hoffart, 2001; Hoffart & Sexton, 2002). Two of these studies had no control conditions (Gude, Monsen & Hoffart, 2001; Hoffart & Sexton, 2002) and also demonstrated relatively low treatment effects compared to the other ST studies discussed in this review. However, without a control condition it is difficult to make any inference about ST specifically, as the benefits may be due to other factors such as psychological contact or the inpatient environment. The other study had a control condition that differed in type of group (one was open the other closed) content, structure and possible behavioural experiments (Gude & Hoffart, 2008). Although any one of these differences may have influenced the difference in outcomes, this study demonstrated large effect sizes in the ST group compared to low to medium effects in the control group. Another important note made by the authors was in reference to the different data collection procedures used. The comparison group were sent the follow-up questionnaires by post whilst the ST group had personal interviews. It is known that personal interviews can result in more favourable outcomes due to the potential of participants wanting to please the researcher (Moum, 1998).

Overall, the lack of control groups in these studies makes it difficult to draw clear conclusions. However these initial promising findings suggest that future research in this field is warranted.

Dual focus schema therapy for substance misuse

Two studies were found that targeted substance misuse and concurrent personality disorders (Ball, 2007; Ball *et al.,* 2005). The research in this area was difficult to review for a number of reasons. Firstly, the authors of this research described difficulties retaining participants and collecting data. Secondly, there was an absence of power calculations which potentially means the sample size may have been too small to detect effects. Thirdly, the main outcome measures were reductions in substance use, not reduction in early maladaptive schemas.

Although ST may benefit individuals who misuse substances, care should be taken to ensure participants are not contra-indicated for therapy. For example, participants should be screened to ensure they are not actively using substances, in a state of acute withdrawal, facing other crises and are stable in other respects (Young *et al.*, 2003). When this is not possible, it must be recognised that such influences may impact on the effectiveness of ST. Future research should also evaluate schema change as one of the outcome measures, as this is the primary goal of ST. Ideally, control groups should be run with an evidenced based treatment alternative delivered in an equally structured, focused and intensive way using the same outcome measures to the ST condition. Practically, this may prove difficult to substantiate within some healthcare organisations where therapies for this population are few and far between. Finally, to achieve high quality research in this area, care should be taken to address the difficulties that were encountered and described by these studies. This will likely involve putting procedures in place to overcome the difficulties found in relation to recruitment, retention and data collection.

Schema therapy for eating disorders

To our knowledge only one pilot study has attempted to look at the effectiveness of ST in an eating disorder population (Simpson *et al.,* 2010). This study had a small number of partipants (8) and no control group. For these reasons clinical recommendations cannot be based on this study alone. Despite this study's small size it benefits from having sound outcome measures including schema severity administered at regular intervals and in a controlled way. Reductions were found in eating disorder severity, anxiety and shame whilst quality of life increased. These benefits resulted in large effect sizes at the six month follow up. The benefits of this pilot study demonstrate that further research is warranted in this area. Future research should use a control condition to ensure that the benefits were attributable to the ST component rather than other factors (such as a well run, structured and closed group).

Summary and recommendations

Overall this review highlights the gap between the clinical popularity of schema therapy and the evidence base. Within the current economic climate, without a strong evidence base it may become difficult for clinicians to justify the use of any therapy. In order to establish itself as an evidence based treatment, clinicians and researchers of the ST model need to plan and implement studies of a similar methodological standard to the study by Giesen-Bloo *et al* (2006). Over the next few years a number of important studies are expected to be published which shall be awaited with interest. These include a large multi-site study of ST in forensic settings and an international study looking at group and individual ST for individuals with BPD.

Despite the relatively few studies published on the effectiveness of ST, what is noticable are the relatively large effect sizes. ST appears to display larger effects than are generally found in psychotherapies for personality disorders (Perry, Banon & Ianni, 1999; Leichsenring & Leibing, 2003). This finding provides strong rationale to continue developing and expanding the research in this field. However, as treatment effects can be influenced by study design and methodology, it is important to control for such factors. Overall, the area appears to benefit from using good screening and assessment measures but needs to focus on some key areas. These are:

1. Using power calculations when planning sample size.

2. Ensuring control groups are as similar to the ST condition as possible to reduce the possibility that differences are due to non-therapeutic effects such as frequency of contact, duration, intensity etc. This will ensure the effects can be attributed to the therapy and not other factors.

3. Planning quality assessments and ensuring regular ST training and supervision for the therapists.

4. Measuring schema change as an essential outcome measure.

5. Ensuring the intervention is accessible to clinicians by exploring time frames and formats that can be implemented within clinical psychology services in healthcare organisations. As previously mentioned, this may include looking further at ST groups or using single case experiments in routine practice as an alternative way of gathering data.

Finally, as there is a large amount of literature testing the theoretical basis for ST, a theoretical review of ST would make an interesting and clinically useful contribution to the literature.

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Chapter Two

Introduction to Major Research Project

Exploring the Relationship Between Schema Modes, Cognitive Fusion and Eating Disorders.

Summary

Integral to the role of clinical psychologists working within the NHS is ensuring that they are providing evidence based treatments and interventions. A vital part of this is exploring new treatment models and approaches. Currently, the recommended treatment for Bulimia Nervosa (BN) is Cognitive Behavioural Therapy (CBT) (Hay *et al*., 2009a). Despite this, less than half of people with BN recover following a course of CBT (Agras *et al*., 2000). The longer term follow up is even less encouraging with almost a third continuing to suffer (Agras *et al*., 2000). The most recent Cochrane review compared the effectiveness of a range of therapies for Anorexia Nervosa (AN). It concluded that no specific treatment approaches could be recommended for the outpatient treatment of AN (Hay *et al.*, 2009b). These findings highlight the need for clinicians working in this field to look at enhancing research in this area and possibly looking for alternative therapeutic approaches that better meet the needs of their patients with eating disorders.

The primary aim of this research is to explore whether two relatively new therapeutic models; schema therapy (Young *et al.,* 2003) and acceptance and commitment therapy (ACT) (Hayes *et al.,* 1999) may enhance our understanding of eating disorders. Although both models have recently become increasingly popular they are theoretically and practically very different. Theoretically, schema therapy assumes that mental health difficulties are associated with early maladaptive schemas (Young *et al.,* 2003). Broadly speaking these are unconditional and dysfunctional beliefs about the self that are developed during childhood.

A schema therapist would typically use questionnaire measures and imagery techniques to help individuals identify early maladaptive schemas. When identified, a schema therapist

would work with the individual to try and reduce maladaptive schemas and increase the strength of adaptive ones.

In comparison, ACT suggests that mental health difficulties are associated with psychological inflexibility (Hayes, 2004). ACT therapists may use various assessment tools to help them identify forms of psychological inflexibility, when identified, ACT therapists would then apply mindfulness, acceptance and commitment techniques to increase psychological flexibility.

In ACT, one component of psychological inflexibility which is currently been investigated is cognitive fusion. Cognitive fusion refers to excessive or improper regulation of behaviour by verbal processes (Hayes *et al.,* 2006). A recent addition to schema therapy is the concept of schema modes. Modes are seen as clusters of schemas which are activated simultaneously.

Questionnaires have been developed to help therapists assess both schema modes and cognitive fusion. This research will look at the relationship between eating disorder severity and these measures. If relationships are found between eating disorder severity and either of these measures then this would further contribute to our understanding of eating disorder symptoms.

Introduction to Eating Disorders

Although there are various forms of eating disorders this thesis will focus exclusively on Anorexia Nervosa, Atypical Anorexia, Bulimia Nervosa and Atypical Bulimia according to ICD-10 diagnostic criteria.

Anorexia Nervosa

Anorexia Nervosa (AN) is a syndrome in which the individual maintains a low weight (at least 15% below what is expected) as a result of a pre-occupation with body weight construed either as a fear of fatness or pursuit of thinness (NICE, 2004). Weight is lost via a variety of means such as avoiding 'fattening foods', excessive exercising, self-induced vomiting or misuse of laxatives (NICE, 2004). The effects of poor nutrition can result in amenorrhoea in women and lack of sexual interest or potency in men. In younger children, puberty is frequently delayed whilst physical growth and development are usually stunted (NICE, 2004). Individuals suffering from AN often view weight control as highly desirable. Subsequently they may view their weight loss as a positive achievement and deny the seriousness of the condition (NICE, 2004).

AN typically starts with dieting behaviour that may evoke little or no concern. A smaller proportion may develop AN following a viral illness which resulted in weight loss. In some individuals this can became positively valued and therefore develop into an anorexic illness (NICE 2004). Unfortunately, the commitment to dieting appears to increase in AN and subsequently a number of secondary features often develop. These might include social withdrawal, anxiety and depression (NICE, 2004). These may be particularly likely if these traits were previously features of the individual's personality. These secondary features then predispose the individual to develop a host of other difficulties such as

physical or health complications, social isolation, impediment of educational and employment plans and reduced functioning (NICE, 2004).

The most up to date review of the epidemiology of AN was conducted by Hoek & van Hoeken in 2003. Based mainly on studies from Europe and the USA, this study demonstrated an average prevalence rate for AN of 0.3% amongst women.

The course of AN is variable. For some, AN many have a chronic course with notable psychiatric and medical co-morbidities (Fairburn & Brownell, 2001). Common co-morbid psychiatric problems include depression and para-suicidal behaviour, anxiety disorders, obsessive–compulsive disorder and alcohol and substance misuse (Simon *et al.*, 2005; Zipfel *et al.,* 2003). Physical complications include cardiovascular problems, renal problems, gastrointestinal disturbance, fluid and electrolyte abnormalities, menstrual and fertility problems, osteoporosis and osteopenia, and dental and dermatological abnormalities (Simon *et al.*, 2005; Zipfel *et al.* 2003).

In relation to recovery, a review of 68 studies published before 1989 found that approximately 43% of sufferers will recover completely from the disorder (Steinhausen, 2002). A further 36% will somewhat improve whilst 20% developed a more chronic eating disorder. The remaining 5% died from anorexia. The overall mortality in the studies included in this review ranged from 1-21% and were due to a combination of physical health complications and suicide (Steinhausen, 2002). More recent studies have estimated the 'all cause' mortality for AN to be three times higher than other psychiatric conditions such as depression, and schizophrenia (Nielson, 2001), and three times higher than alcoholism (Harris & Barraclough, 1998).

A further concern is the proportion of individuals with AN that go on to develop a different eating disorder such as bulimia or binge eating disorder (NICE, 2004). The incidence of AN appears to be stable overall, but may be increasing in younger age groups (Nicholls, Lynn & Viner, 2011). As with adults, the prognosis of AN in children and adolescents appears variable (NICE, 2004). When the onset is both early and rapid, individuals may be more likely to make a full recovery. This form of AN appears typically to be in response to an identifiable life event such as bereavement (North *et al.,* 1999). More insidious onsets embedded within earlier social/emotional difficulties, appear more likely to develop into a chronic course (Gowers *et al.,* 1994).

Bulimia Nervosa

There are fewer studies looking at the course and outcomes of Bulimia Nervosa (BN) in the community than AN. This may in part be due to the lower level of physical and health complications associated with this condition (NICE, 2004). However, BN is still considered to be a serious and debilitating condition characterised by recurrent episodes of binge eating followed by compensatory behaviour such as vomiting, purging, fasting or exercising in order to prevent weight gain (NICE, 2004). As in AN, self-evaluation is believed to be unduly influenced by body shape and weight. However in BN, the individual is able to maintain a body mass index above 17.5 kg/m2 (NICE, 2004). Additionally, whilst an individual with AN is likely to value their condition, individuals who binge and purge typically experience feelings of guilt and shame. It is common for individuals starting treatment to feel a level of ambivalence. For example, they may fear that if they are prevented from purging they will gain excessive weight (NICE, 2004).

Mood disturbance is extremely common in BN and symptoms of anxiety and tension are frequently experienced (NICE, 2004). Individuals may also develop negative thoughts and

disgust relating to their overeating or purging behaviour. Self-harm is also common. Importantly, a significant proportion of those with BN have a history of disturbed interpersonal relationships with poor levels of impulse control (NICE, 2004).

Estimates of the prevalence of BN in the community suggest it occurs in 0.5 - 1 % of the population (Hay & Bacaltchuk, 2001). A more recent review of the epidemiology suggest that the prevalence rate of BN is 1% for young women and 0.1% for young men (Hoek & van Hoeken, 2003). As in AN, there is a higher prevalence of BN in women with approximately 90% of sufferers being female (Hay & Bacaltchuk, 2001).

Unfortunately, it is estimated that the majority of individuals with BN do not receive any form of help (Hsu, 1995). Despite this, when help is sought, recovery from BN appears higher than AN with some treatments resulting in 50% of people being asymptomatic between two and ten years after assessment (Hsu, 1995). A further 20% will continue to suffer from the full form of BN whilst the remaining 30% appear to experience recurrent remissions / relapses or persistent sub-diagnostic BN (Hsu, 1995). Although BN does not have as much of an impact on physical health and mortality rates as AN, it is anticipated that mortality is higher than in the matched general population (Hsu, 1995).

Atypical Eating Disorders

There are a significant number of individuals who have clinically significant eating disorders that do not meet the precise ICD-10 diagnostic criteria for AN or BN (Fairburn & Harrison, 2003). In Europe, these individuals are often given ‘atypical’ eating disorder diagnosis (Fairburn & Harrison, 2003).

Economic Impact of EDS

Whilst the mortality and physical complications of these disorders are well recognised, the negative impact on quality of life and other social, occupational and economic costs have received far less attention (Keilen *et al.,* 1994). The chronic nature of eating disorders and the numerous co-morbidities and complications suggest that people with eating disorders are high consumers of medical and social care (Simon *et al.*, 2005). A systematic review conducted by Simon, Schmidt & Pilling in 2005 demonstrated how eating disorders are general under-detected and under-treated. They acknowledged that the economic burden is likely to be substantial (Simon *et al.,* 2005). In the UK the National Health Service cost of AN was estimated to be £4.2 million per annum in a prevalence-based cost-of-illness study in 1990 (Office of Health Economics, 1994). However, this estimate was described as conservative due to not attempting to account for the potentially substantial costs of out-patient care (including psychological therapies) and private eating disorder services. (Simon *et al.,* 2005). Interestingly, there are no more recent UK estimates for AN; nor are data available for BN or atypical diagnosis.

Evidence Base for Treatment of Eating disorders

The most recent Cochrane review on the outpatient treatment for AN was completed in 2009. Although AN has been demonstrated to be a severe, disabling and relatively common disorder, what is apparent from this review is the lack of strong evidence for effective outpatient treatments (Hay *et al.*, 2009b). Only seven trials were included in the review and these appeared to be testing a variety of different types of psychotherapy. Overall the authors stated that they were unable to make firm conclusions about the therapies tested based on the current evidence base (Hay *et al.*, 2009b). This is disappointing given the demonstrated need to find effective treatments for this group of individuals. It is important to acknowledge that Cochrane reviews use rigorous quality

assessment criteria and therefore only include the very strongest evidence. This process may exclude some smaller studies that might still provide useful information on psychological treatments. What the authors were able to conclude was that participants who did not receive psychotherapy (e.g. were in a waiting-list control group or who got 'treatment as usual') did poorly. In one study, all those in the control group who got only 'dietary advice' dropped out (Hay *et al.,* 2009b). This information highlights the need for effective treatments to improve outcomes for this group of individuals. Overall, this systematic review concluded that there is an urgent need for multi-centre, large scale randomised controlled trials of commonly used psychotherapies in older adolescents and adults with AN (Hay *et al.,* 2009b).

The most recent Cochrane review on BN (Hay *et al.*, 2009a) reviewed studies of psychotherapies, including a specific form of cognitive behavioural therapy for BN (CBT-BN). The authors compared psychotherapy to control groups who got no treatment (e.g. people on waiting lists) and the specific CBT-BN with other types of psychotherapy. Unlike the review for AN, this review found evidence to suggest that CBT was better than other therapies, and better than no treatment, at reducing binge eating (Hay *et al.*, 2009a). However, it was recommended that more research and larger trials are still needed to improve outcomes for individuals with BN.

To date, the Scottish Intercolegiate Guidance Network (SIGN) have not produced any reviews or guidance in relation to eating disorder treatment. However, there are some National Institute for Clinical Excellence (NICE) guidelines that recommend cognitive behavioural treatment (CBT) for the treatment of eating disorders (NICE, 2004) and also Quality Improvement Scotland guidelines that predominantly recommend CBT (NHS-QIS, 2006). The main goals of CBT for BN includes normalisation of eating, reducing attempts

to diet, eliminating binge eating and purging, and altering beliefs, thoughts and values which maintain the eating problem (NICE, 2004; NHS-QIS, 2006). The same protocol can be used for those suffering from anorexia with only minor variations and typically an extended time frame (Juarascio, Forman & Herbert, 2010).

Most significant benefits have been observed in the reduction of binge eating, purging, and other compensatory behaviors used by individuals with bulimia to control their weight (Fairburn, 2008; Treasure *et al.,* 1994). Despite these recommendations a relatively large subset of individuals do not achieve any clinically significant benefit from CBT (Juarascio, Forman & Herbert, 2010). In fact some studies demonstrate only 30-50% of patients cease to binge and purge using this approach (Fairburn 2008; Wilson, 2005; Wilson, *et al.,* 2007). The outcomes for anorexia, have been even less encouraging (Wilson, 2005; Hay *et al.*, 2009b). These findings suggest that although CBT may benefit some individuals, there are still a large proportion of individuals whose needs have not been adequately met.

There are a number of reasons why CBT might not be best suited to treat eating disorders. Firstly, patients with eating pathology (particularly those with anorexia) might have little desire to change (Juarascio, Forman & Herbert, 2010). The eating disorder may be viewed as something that has helped them to lose weight which might be a valued achievement (Vanderlinden, 2008). Secondly, CBT directly attempts to change the content of unhelpful eating-related cognitions. The nature of eating disorder cognitions may make them particularly resistant to direct modification efforts. This is due to difficulties set-shifting (Roberts *et al.,* 2007) and cognitive rigidity which may make cognitive challenging particularly difficult (Guarda, 2008). Thirdly, many eating disorders may be functional within the context of the patient's belief system (Juarascio, Forman & Herbert, 2010). An

example would be when someone believes they are overweight and thus find eating pathology assists them in weight reduction.

Rationale for completing research in this field

Due to the limited efficacy of psychological therapies for individuals with eating disorders the evidence base needs to be developed further so that clinicians can better meet the needs of their patients. This project is interested in exploring how psychological constructs from ST (schema modes) and psychological processes from ACT (cognitive fusion) relate to eating disorder symptoms.

Schema Therapy

Three main concepts are central to ST. The first is that of early maladaptive schemas. Broadly speaking these are unconditional and dysfunctional beliefs about the self that are developed during childhood. These commonly develop in children living within an environment which fails to meet their core emotional needs, or where they experience repeated episodes of abuse, neglect, hostility and criticism (Young *et al.*, 2003). The second concept central to ST is that behaviours are embedded within early maladaptive schemas. Young states that a person can maintain early maladaptive schemas using three main coping strategies; overcompensation (fighting the schema and acting as though the opposite were true), surrendering (or giving in to the schema) and avoidance (trying to avoid schema activation) (Young *et al.*, 2003). The third concept relates to schema modes. These are the most recent advance to ST and reflect the emotional and behavioural state of a person at a given time. Modes comprise of clusters of schemas activated simultaneously. ST and schema mode therapy do not reflect two separate entities, rather schema mode work is seen as an advanced component of ST.

The mode model provides a valuable framework to understand and work therapeutically with people with complex personality pathology or entrenched and chronic problems (Young *et al.*, 2003). The aim is to strengthen healthy modes and weaken the impact of the maladaptive ones (Young *et al.,* 2003). Broadly speaking there are three groups of modes; child modes, dysfunctional coping modes and dysfunctional parent modes. These shall now be described.

The child modes are thought to be innate and are moulded by a combination of childhood experiences and environmental factors. The *Vulnerable Child* mode is considered the most important for schema mode work (Young *et al.*, 2003). When activated the

Vulnerable Child elicits strong emotional responses in the individual such as anxiety, fear, sadness, and helplessness. The *Angry Child* mode relates to the frustration of a young child whose core needs have not been met. When activated in adulthood, the individual may react to experiences where their needs have not been met with similar expressions of anger at the perceived injustice. This mode is associated with schemas such as abandonment, mistrust/abuse, emotional deprivation and subjugation (Young *et al.,* 2003). The *Impulsive/Undisciplined Child* mode relates to children who learned to meet their own needs by behaving impulsively with little concern for others. When activated in adults, the individual will struggle to tolerate frustration and feel unable to delay gratification. Individuals with this mode may therefore struggle to achieve long-term goals and may present as spoilt, careless, impatient, unfocused or out of control (Young *et al.,* 2003). The last child mode is called the *Happy Child*. This is not seen as a dysfunctional mode, rather it is reflective of the child who feels loved and contented. When activated in adulthood this mode will trigger positive emotions.

The coping modes correspond to the schema processes of surrender, avoidance and overcompensation outlined earlier. The surrender coping strategy is characterised by the *Compliant Surrenderer* mode. When activated this mode will result in the individual acting in a passive, subservient, submissive, approval-seeking, or self-deprecating way around others out of fear of conflict or rejection. This mode may result in the individual tolerating abuse and/or bad treatment and may prevent the person from expressing healthy needs or desires. The avoidance coping strategies are depicted by the *Detached Protector* and the *Detached Self-Soother* modes. The *Detached Protector* refers to the psychological withdrawal of individuals by disconnecting from others and acting in an almost robotic manner to shut off emotions (Young *et al.,* 2003). The *Detached Self-Soother* mode is also an avoidant strategy whereby individuals shut off their emotions by engaging in activities that will soothe or distract them from feeling. The schema mode that relates to the

schema process of overcompensation is called the *Self-Aggrandiser* mode. When activated the individual may feel and behave in a grandiose, aggressive, dominant or status-seeking way. These feelings and behaviours originally developed to compensate or gratify for early unmet core needs (Young *et al.,* 2003).

Finally, the parent modes represent the internalised experience of overly critical or demanding parents. When activated the *Punitive Parent* mode results in the individual feeling that they or others deserve punishment or blame. This often results in them acting in a blaming, punishing, or abusive way towards themselves or others. The *Demanding Parent* mode results in the individual feeling that there is a "right" way to be. For example, they may feel that they need to be perfect or achieve at a very high level or that it is wrong to express feelings. The last mode is called the *Healthy Adult*, like the *Happy Child* it is seen as a functional mode characterised by an individual performing appropriate adult functions (Young *et al.,* 2003).

Schema Therapy and Eating disorders

As has been previously described, eating disorders are often associated with a variety of other challenges including co-morbid personality disorders (Vrabel *et al.*, 2010), difficult interpersonal relationships and difficulty tolerating emotional experiences (Linehan, 1993). Although not always the case, for some individuals these may reflect early experiences of living within environments which failed to meet their core emotional needs. In particular there has been associations found between eating disorders and childhood sexual abuse, physical and emotional abuse (Kent, Waller, & Dagnan, 1999; Rorty, Yager, & Rossotto, 1994; Smolak & Murnen, 2002; Wonderlich *et al.,* 2001). These experiences can be likened to the 'toxic experiences' referred to by Young *et al.*, (2003). For such individuals understanding these developmental and environmental influences and the resulting schema modes may help clinicians to better understand the eating disorder behaviour.

Although no research has directly explored the relationship between schema *modes* and eating disorders, previous research has looked at the relationship between schemas and eating pathology. Firstly, Leung *et al.,* 1999 demonstrated that women with eating disorders held more dysfunctional schemas than control women. Additionally, different patterns of schemas were observed in anorexic and bulimic women suggesting that particular schemas may be associated with particular eating behaviours (Leung *et al.,* 1999). Although Leung *et al.,* (1999) were the first to propose a link between eating disorders and early maladaptive schemas, this relationship has since been supported by Waller *et al.,* (2000 & 2002).

As well as supporting Leung's findings these studies also demonstrated that certain schemas were predictive of levels of eating disordered behaviour. For example, the frequency of binging was associated with the *emotional inhibition* schema whilst the frequency of vomiting was associated with *defectiveness/shame* schemas (Waller *et al.*, 2000; 2002). Waller *et al.* (2002) concluded that bulimic women binged more often if they deemed the expression of emotion to be unsafe or unacceptable. Additionally, they were more likely to vomit if they believed themselves to be fundamentally flawed or defective. This conclusion is compatible with the suggestion that vomiting serves the function of reducing awareness of aversive cognitions, whereas binging serves more of an affect regulation function (Pitts & Waller, 1993). The implication of these findings is that each individual may need tailored treatments specifically targeted towards their individual needs. Thus a generic treatment package may be ineffective.

Together these findings suggest that restrictive eating is associated with perceptions of the self as being dependent, incompetent and unable to express emotions. Bulimic attitudes were found to be associated with women who viewed themselves as being deprived of emotional support, socially different, and lacking self-control (Waller *et al.*, 2002). Overall, the schemas most associated with unhealthy eating patterns were found to be *Dependence, Emotional Inhibition, Emotional Deprivation, Social Isolation* and *Insufficient Self-control*.

Although these studies provide evidence to link theoretical elements from schema theory to individuals with eating disorders some limitations must be considered. Firstly, although the importance of schema level cognitive beliefs in eating disorders may have been supported this evidence does not allow differentiation between AN or BN. This either means that individuals with eating disorders have similar schemas or the instruments used to assess schemas are failing to identify these differences. As behavioural characteristics are usually measured to assess for improvement, a measure that is able to measure these differences would be preferable. Secondly, all three studies failed to screen for affect disorders. It could be argued that affect disorders may account for some of the variability found in schemas and thus be reflecting general psychopathology found within a range of clinical populations rather than eating disorder specific pathology. Thirdly, all these studies have relatively small sample sizes which reduces the generalisability of these findings.

The most recent hypothesis put forward by Waller (submitted) is that restrictive and bulimic pathologies are both related to affect regulation. The key difference between anorexic and bulimic pathologies is the point at which the individual makes an attempt to reduce the experience of intolerable negative affect (Waller, submitted). In restrictive pathology the individual is hypothesised to use primary avoidance and subsequently may attempt to avoid the affect being triggered at all. In primarily bulimic pathology it is hypothesised that

the individual may use secondary avoidance strategies which attempt to reduce affect that has already been triggered (Waller, submitted).

This understanding of eating disorders is at odds with the current ICD-10 diagnostic system. Rather than categorising the disorder in terms of AN and BN, Waller proposes that the emphasis be on whether the disorder is primarily restrictive or bulimic. This alternative way of categorising eating disorders appears to be related to the key psychopathological characteristics associated with binging and purging and the key characteristics of restriction. Waller's schema based model of eating disorders has been tested empirically by Luck *et al.* (2005). In total, 345 non clinical participants completed the Young-Rygh Avoidance Inventory (YRAI; Young, 1994) and the Young Compensatory Inventory, (YCI; Young, 1998). The results of this study indicated that primary avoidance strategies were found in the anorexic disorders, while only secondary avoidance processes were found in the bulimic disorder.

Overall, difficulties in regulating emotion appear may be a key factor in maintaining eating disorders for some people (Corstorphine, 2008). Affect regulation difficulties are not a new concept in the field of eating disorders and have previously been discussed by a number of authors (Linehan, 1993; Fairburn *et al,.* 2003; Corstorphine, 2006; Abraham & Beumont, 1982; Lacey, 1982; McManus & Waller, 1995; Meyer, Waller, & Waters, 1998). Previous research has demonstrated that individuals with an eating disorder may report difficulties tolerating strong affect (Corstorphine *et al.,* 2005; Wiser & Telch, 1999). This difficulty may subsequently result in them attempting to avoid emotional activation or experiences (Serpell & Treasure, 2002; Serpell *et al.,* 1999). As eating behaviours can serve the function of managing strong emotions (Root & Fallon, 1988; van der Kolk & Fisler, 1994), it might by hypothesised that severity of eating disorders may be associated with the coping

modes discussed earlier (the *Detached Protector, Detached Self-Soothe*r and the *Compliant Surrender*).

A recent review of the evidence base for ST (Masley *et al.,* submitted) found only one study that has applied ST to individuals who had an eating disorder (Simpson *et al.*, 2010). In this study, the effectiveness of group ST was empirically tested in an outpatient eating disorder service. Despite the small size of this study, it benefited from having sound outcome measures administered at regular intervals and in controlled way. Reductions were found in eating disorder severity, anxiety and shame whilst quality of life increased. These benefits resulted in large effect sizes at a six month follow up. The benefits of this pilot study demonstrate that further research is needed into the potential benefits of using ST in the treatment of eating disorders (Simpson *et al.,* 2010).

Although no published study has explored the relationship between eating disorders and schema modes, previous unpublished research by Jenkins (2009) looked at whether schema modes differed between a clinical and control population. This research supported Waller's hypothesis that the coping modes (*Detached Protector, Detached Self-Soother* and the *Compliant Surrender*) were characteristic modes in an eating disorder population. Additionally, Jenkins also found evidence to suggest that the *Vulnerable Child* mode was also associated with eating disorders (Jenkins, 2009). Although this research was able to demonstrate that particular schema modes were more prevalent in an eating disorder population, it failed to look at the relationship between eating disorder symptoms and schema modes. This will be a primary aim of this study.

Acceptance and Commitment Therapy (ACT)

The ACT approach is considered a third generation cognitive behavioural approach (Hayes, 2004). ACT conceptualises language as having a key role in how individuals respond to their environment, both external and internal. An individual whose behaviour is bound by rigid cognitive processes and beliefs may be considered to have reduced 'psychological flexibility'. ACT proposes that psychological inflexibility can be a primary source of (and maintaining factor in) psychopathology (Hayes, 2004). Briefly, psychological flexibility is often used to describe the combination of two key components of ACT theory; cognitive fusion and experiential avoidance.

Cognitive fusion has been described as the process by which thoughts about an event become fused with the actual event (Wicksell *et al.,* 2008) and also as the excessive attachment to the literal content of thought that makes healthy psychological flexibility difficult or impossible (Hayes*,* 2004). Therefore individuals with high cognitive fusion are more likely to fuse themselves and their identity with their language system and experience. For example, an individual may say 'I am depressed'. This statement looks like a description but in reality it demonstrates an individual has fused themselves with the verbal label. When an individual has used language in a way that appraises feelings of depression, anxiety and pain as wrong, experiential avoidance is more likely to occur. Experiential avoidance is anything the individual does to avoid being in contact with a distressing aspect of a private experience (e.g. anxiety). Based on this assumption, individuals may try to avoid some experiences altogether which starts to limit the activities an individual will engage in. Cognitive fusion alone is unlikely to generate psychopathology but when it is associated with avoidance strategies it starts to become problematic.

It is anticipated that individuals with high levels of cognitive fusion will have poor psychological flexibility and psychological inflexibility is associated with the development and maintenance of psychopathology. This study will assess if eating disorder severity is associated with high levels of cognitive fusion. Again, if theoretical links are found this provides rationale to continue on to conduct clinical trials assessing the treatment effectiveness of the model within eating disorder populations.

ACT and Eating Disorders

ACT states that peoples behaviours are changeable whilst internal experiences are less so (Hayes, Strosahl & Wilson, 1999). Therefore rather than seeking to modify internal experiences, ACT promotes acceptance of cognitions and feelings because attempting to control unwanted experiences is often ineffective if not counter-productive (Hayes, 2004). Conceptualisation of eating disorders from an ACT perspective would state that the eating disorder serves a function to the individual (Pearson *et al.,* 2011). This function is commonly to either avoid difficult uncontrollable emotions (Pearson *et al.,* 2010; Pearson *et al.,* 2011) or serves an experiential avoidance function (Bryne *et al.,* 2003; Heffner *et al.,* 2002). As has been previously stated, psychological flexibility and cognitive fusion are often associated with non-acceptance of emotion and experiential avoidance. This link has been supported in the field of eating disorders by Lillis *et al.,* (2009) who found that acceptance and greater psychological flexibility was associated with healthier eating habits and lower levels of weight related shame. Conversely, non-acceptance of emotional experience has been associated with dietary restraint (Merwin *et al.*, in press) and rigid inflexible beliefs with body dissatisfaction and disordered eating (Sandoz, 2010).

The role of emotions in eating disorders is not a new concept and certainly not exclusive to ACT. In many ways these findings fit well with those of Waller *et al.*, (2002) previously discussed. However, despite some theoretical overlap, the treatment approaches of schema therapy and ACT differ substantially.

Heffner *et al.,* (2002) developed a treatment protocol for using ACT with individuals who have an eating disorder. As with most ACT approaches the first step is to elicit a sense of creative hopelessness (Hayes, 2004). This is typically achieved by demonstrating that previous strategies designed to reduce feelings of body dissatisfaction have not been effective in that they still have concerns about weight despite using eating disorder strategies (Hayes, 2004). Therapists might move on to discuss the impact that trying to control distressing feelings has had on individuals. This might include highlighting the reduced freedom and increased distress trying to maintain the eating disorder has caused. Eventually, the therapist seeks to demonstrate that current strategies may not be the most workable solutions and subsequently suggest an alternative approach which would likely involve a degree of acceptance of the distress and a willingness to make behavioural change despite it (Juarascio, Forman & Herbert, 2010).

ACT places a strong emphasis on an individual's unique values and goals. A value is seen as an important and chosen life direction and hence will provide the context for specific treatment goals or targets. Patients are taught that distress tolerance is not an end in and of itself, but rather a means to the end of engaging in valued behaviours (Juarascio, Forman & Herbert, 2010). As ACT is a type of behaviour therapy, standard behavioural approaches to eating disorders (e.g., exposure, self-monitoring) can be integrated easily within the treatment (Juarascio, Forman & Herbert, 2010).

Previous research has suggested that two central components of ACT, acceptance and mindfulness, are associated with better treatment outcomes for individuals who have an eating disorder (Juarascio, Forman & Herbert, 2010; Kristeller, Baer, & Quillian-Wolever, 2006). The study by Juarascio, Forman & Herbert, 2010 looked at whether ACT or traditional CBT would be more effective in treating eating disorders. Overall, ACT (pre to post-treatment Cohen's d = 1.89) was shown to be superior to CBT (d =0.48) at reducing problem eating behavior (Juarascio, Forman & Herbert, 2010). Although ACT and CBT share many of the same non-specific therapeutic effects and some similar behavioral techniques, there are several ways in which they differ. This study reinforces previous studies that suggested that core strategies of ACT, i.e., increasing acceptance, mindfulness, willingness, and distress tolerance, may be useful ways to promote change in individuals with eating symptomotology (Baer, Fischer, & Huss, 2005; Kristeller, Baer, & Quillian-Wolever, 2006.

Another study looked at the role of interoceptive awareness in eating disorders (Merwin *et al.,* in press). Interestingly this study found evidence to suggest that negative reactions (such as non-acceptance) to emotional responses may contribute to dietary restraint (Merwin *et al*., in press). ACT has also been shown to be helpful both with weight related self-stigma and with weight maintenance (Forman & Herbert, 2009; Lillis *et al.,* 2009; Tapper *et al*., 2009) and has been applied in case studies to those with eating disorders (Heffner *et al.,* 2002). Psychological inflexibility has been associated with body image dissatisfaction and disordered eating (Sandoz, 2010) and most recently, ACT has also been shown to improve eating attitudes, reduce body anxiety and reduce preoccupation with weight and shape (Pearson *et al.,* 2011).

At its core ACT attempts to promote acceptance of emotional responses and internal experiences thus potentially increasing the viability of this model in working with individuals with eating disorders. Although ACT has various components, this study is interested exclusively in whether cognitive fusion is associated with eating pathology. Cognitive fusion is a pivotal concept in ACT and if it is found to be related to eating disorders it would further increase our understanding of eating disorders.

Chapter Three

Research Aims

This research has one primary aim:

To look at the relationship between maladaptive schema modes and eating disorder severity.

- It is hypothesised that there will be a positive relationship between the mean maladaptive schema mode score and mean EDE-Q score. Additionally, it is hypothesised that the coping modes (*Detached Protector, Compliant Surrenderer and Detached Self-Soother)* as well as the *Vulnerable Child* mode will be characteristic modes of the eating disorder population.

This project has two secondary aims:

1. To determine the extent that cognitive fusion is associated with eating disorder severity.
    - It is hypothesised that there will be a significant positive relationship between the process of cognitive fusion and eating disorder severity.

2. To determine whether the severity of maladaptive schema modes predicts eating disorder severity independent of cognitive fusion or whether the process of cognitive fusion mediates this relationship?

3. To determine which of the schema modes best predicts eating disorder severity.

Chapter Four

Methodology

Participants

Participants were recruited from two health boards within Scotland; NHS Highlands and Grampian. Within NHS Grampian there was an inpatient and outpatient service. Potential participants needed to have met the following inclusion criteria:

- Participants had a diagnosis of Anorexia Nervosa, Atypical Anorexia Nervosa, Bulimia Nervosa or Atypical Bulimia Nervosa according to ICD−10 diagnostic criteria. This was assessed by a trained clinician working within the various specialist eating disorder services.

- Participants were between the ages of 18 and 65 years.

- Participants already engaged in treatment had not had more than five ACT or schema therapy sessions.

- Participants had good command over the English Language to complete the questionnaires.

Measures

All participants were asked to complete the following three questionnaires;

- *The Schema Mode Inventory, (SMI-1.1), (Young et al., 2007)*

The SMI-1.1 measures the presence of 14 schema modes (Appendix A). These modes include *Vulnerable Child, Angry Child, Enraged Child, Impulsive Child, Undisciplined Child, Happy Child, Compliant Surrenderer, Detached Protector, Detached Self-Soother, Self-Aggrandizer, Bully and Attack, Punitive Parent, Demanding Parent* and *Healthy Adult* (Young *et al*., 2007). Schema modes can be clustered into four categories: dysfunctional child modes; coping modes; parent modes and two healthy / adaptive modes (*Healthy Adult and Happy Child*). The SMI-1.1 is a self- report measure containing 124 items designed to detected the presence and severity of these modes.

When scoring the SMI-1.1, each item contributes to one of the modes. Some modes have more items or questions than others. To get an overall score for each mode, all the items that contribute to the mode are added together and divided by the number of items. This provides a mean score for each mode. Generally speaking, higher scores reflect more maladaptive or significant modes except on the two adaptive modes (Healthy Adult and Happy Child) where higher scores are viewed as more adaptive.

The norms for the SMI-1.1 are based on a study conducted by Lobbestael *et al.* (2010). In this study 863 individuals made up of non patients and axis I and axis II patients completed the SMI allowing the psychometric properties of the questionnaire to be evaluated. Overall, this study found that the SMI had an excellent fit with the 14 factor mode (CFI = .98). Additionally, this study demonstrated the SMI had good internal consistencies on the sub-scales or modes (Cronbach's alpha ranged from .76 to .96, mean = .86) (Lobbestael *et al.,* 2010). Furthermore, inter-correlations between the sub-scales were considered moderate to high, construct validity was reported as reasonable and the test–retest reliability was described as excellent (mean ICC = .84) (Lobbestael *et al.,* 2010). Finally, the authors found good discriminate validity and moderate convergent validity (Lobbestael *et al.,* 2010). Overall, the psychometric results indicate that the SMI is a valuable measure that can be of use for schema mode assessment.

- *Eating Disorders Examination Questionnaire (EDE-Q), (Fairburn & Beglin, 1994)*

The EDE-Q (Appendix B) is a self-report questionnaire used to assess the attitudes and behavioural features of individuals diagnosed with an eating disorder (Fairburn & Beglin, 1994). The EDE-Q is derived from the Eating Disorders Examination (EDE) (Fairburn & Cooper, 1993). The EDE has been extensively researched and it is considered the 'gold standard' for the assessment of eating disordered pathology (Garner, 1995). Despite the EDE being effective in the assessment of eating disordered pathology, it requires specialist training to administer (Fairburn & Beglin, 1994). For these reasons the EDE-Q was developed to provide an efficient, cost effective alternative (Fairburn & Beglin, 1994).

The EDE-Q provides a comprehensive assessment of specific psychopathology of eating disordered behaviour in a 36 item self report format. Various studies have tested the factor structure and the internal consistency of the EDE-Q. In 2007, the EDE-Q was administered to 203 women with bulimic symptoms recruited from five communities (Peterson *et al.*, 2007). This study demonstrated the questionnaire had good internal consistency overall (Cronbach's α = .90), and also on the various subscales (Cronbach's α ranged from .70 to .82). An earlier review completed by Mond *et al*, (2006) on the validity of the EDE-Q noted that a number of studies have found a high level of agreement between the original EDE and the EDE-Q (Mond *et al.*, 2004; Carter, *et al*., 2001; Wilfley *et al.*, 1997; Grilo *et al.*, 2001).

Other studies have shown the EDE-Q to have acceptable internal consistency (Cronbach's α ranged from .78 to .93), test-retest reliability (correlations ranged from r=0.81. to r=0.94) and temporal stability (Luce & Crowther, 1999). Normative data on the EDE-Q sub-scales have also been provided for a binge eating sample (Wilfley *et al.*, 1997) a control sample (Carter *et al.,* 2001) and an anorexia nervosa sample (Passi *et al*., 2003).

- *Cognitive Fusion Questionnaire - CFQ-13, (Gillanders et al., 2010)*

The CFQ-13 is a brief, reliable self-report measure of cognitive fusion (Appendix C). The questionnaire has 13 items which individuals are asked to rate on a 7 point likert scale. Rather than focusing solely on the believability of thoughts the CFQ also has items about literality, engagement with thoughts, perspective taking on thoughts,

entanglement, struggle, and taking action in contrast to thinking (Gillanders *et al*., 2010). The CFQ-13 has shown very good reliability across 4 separate samples of community dwelling adults (total *N* = 1072, Cronbach's *α* = .86). Additionally, it has demonstrated good test-retest reliability over a one month period (*r*=.82, *p*<.001, *N*=74) and has a theoretically coherent factor structure (Gillanders *et al*., 2010).

Finally, preliminary data on the CFQ-13 in clinical samples (total *N*= 169) shows that it has good reliability (Cronbach's *α* .87), can distinguish between people with psychological disorders and healthy participants and correlates as expected with other relevant measures including distress, personality functioning, depression, mindfulness, experiential avoidance and frequency of negative automatic thoughts (Gillanders *et al*., 2010).

Procedure

Individuals were identified through their attendance at one of the aforementioned eating disorder services between April and July 2011. Inclusion criteria was established by a trained clinician working within the specialist services. No participant was included without having first being fully assessed by a trained clinician. When inclusion criteria were established potential participants were approached in different ways. This was due to potential participants having different forms of contact with the services. Some had just been seen for initial assessment, others had been assessed and were on a waiting list for further input and others were in contact with a clinician.

All individuals who met the inclusion criteria were sent information sheets with a cover letter at least 24 hours before being asked if they would like to participate (see Appendix D and E). Participants not in contact with a clinician were sent a slightly different letter (Appendix F) and the information sheet by their primary clinician informing them of the research. These individuals were asked to contact the researcher or clinician directly if interested in discussing the research further. Participants who were in contact with the service were given details directly by their primary clinician and then given the opportunity to talk with the researcher if interested in participating. Individuals who had attended a triage appointment were verbally invited to take part and given the information sheet to take away with them.

Only after expressing an interest, either by directly contacting the researcher or indicating to another clinician they were interested, were participants given the questionnaires or approached by the researcher. Communication was either via telephone, email or an arranged meeting within the eating disorder department they were attending. All participants were given time to read the information sheet and were encouraged to ask the researcher (or their clinician) questions. Following this, individuals who chose to participate were asked to sign a consent form (Appendix G). They were then asked if they would like to complete the questionnaires within the department (with the researcher available if needed) or to take the questionnaires away and complete at home. Participants who chose to take the questionnaires home were given details of a specialist 24 hour eating disorder helpline and also contact numbers for their eating disorder department. This was in case they found the questions emotionally challenging.

Questionnaire completion took approximately 45 minutes on a single occasion. Due to eating disorder symptoms possibly fluctuating over time, all questionnaires needed to be completed together. This meant that participants may have previously completed the same questionnaire(s). This potential repetition was considered necessary to ensure the most accurate account of the individual's current difficulties. Finally, all participants were given the opportunity to request a copy of the final report. To obtain this they provided the researcher with details of where they would like the report to be sent.

After the three-month data collection period ended, questionnaires were scored and data entered into SPSS for analysis. Correlation analyses were used to explore the relationships between eating disorder symptoms, schema modes and cognitive fusion. The results were submitted as part of the researcher's doctorate in clinical psychology.

Scoring the Questionnaires and Dealing with Missing Data

The questionnaires were largely completed with care and seldom were questions left unanswered. On the rare occasion that an item was not completed the following measures were taken. Due to the nature of the EDE-Q, it was not considered appropriate to insert an average score. Very few of the items (12 in total (1%)) were left blank. However, when this was the case, no attempt was made to insert a response due to the potential variability within each subscale. Due to averages not being inserted, the level of eating disorder severity was likely to be slightly

conservative. This was considered preferable to overestimating an individual's difficulties.

On the CFQ-13 and the SMI-1.1 averages were inserted. This was due to the items on these questionnaires being highly interrelated. On the CFQ-13 the items are all associated with cognitive fusion. On the SMI-1.1 each mode is measuring a specific construct so averages were inserted within each mode. For example, if a participant had only completed 9 out of 10 items for one schema mode, the average score for the other items within the mode was inserted.

In general, the majority of the questionnaires had very few incomplete items. In total 39 of the items on the schema mode questionnaires (1%) were based on averages and 4 of the items on the cognitive fusion questionnaire (2%). However, one participant was discovered to have a learning disability after attempting to complete the questionnaires. This participant was unable to complete the majority of all the questionnaires therefore this data was excluded from the analyses. Another participant failed to complete the consent form so this data also had to be removed from the study. No other participant was excluded from analyses.

Confidentiality

All questionnaire packs had a research number that corresponded with the participants consent form. No names or identifiable information were requested on the questionnaires. This ensured that the questionnaires were completely anonymous without the consent form. It was considered important to have a

research number to link the questionnaires to the the consent forms so that should participants wish to withdraw the researcher could identify their data. The researcher was the only person who had access to the participants' personal details. These details (along with the anonymous questionnaires) were kept secure within a locked cabinet in NHS Grampian Outpatient Eating Disorder Service.

The participants were aware that their results would not be shared with other clinicians and that their general practitioner would not be informed of their participation in the study. However, all participants were asked to consent for relevant sections of their medical notes and data from the study to be looked at by NHS Research and Development if the study was audited.

Ethics

Potential risks

All questionnaires have been previously used with clinical groups with no difficulties reported. However, it was considered possible that the questionnaires may identify areas of current difficulty or feeling which participants may not have considered. To ensure individuals had access to adequate support should this situaion arrise all participants were recruited from specialist eating disorder services. Whilst known to the service individuals had access to various avenues of support, for example they could speak with their key worker or lead clinician or other members of the eating disorder team. All services understood the research and agreed to provide support to individuals if needed. Additionally, all individuals were given the opportunity to complete the questionnaires in the department/unit with access to the researcher. If

participants chose to take the questionnaires away they were provided with contact details of the department should they become upset and also details of B-EAT's 24h hour helpline. B-EAT is a national eating disorder charity specialised in supporting individuals with an eating disorder at any time of day or night.

Another concern was participants feeling pressured to take part in the research for fear that their treatment would be effected. To prevent this no participant was approached directly by the researcher but initially was able to take time to read the information sheet. This clearly explained that they were under no obligation to take part and stated that their treatment would not be affected in any way by their decision. If participants wanted to take part they had to contact the researcher directly or request a pack from another clinician in the service. Finally, the time burden to participants was reduced by only including the minimum number of questionnaires. No risks to the researcher or clinicians were identified.

Ethical review

The study was initially reviewed by the Clinical Psychology Ethics Committee at the University of Edinburgh in December 2010. No concerns were raised and the research was passed without amendments. It was then submitted to the North of Scotland Research Ethics Committee on the 27th January 2011. At this meeting it was recommended that the information sheet be simplified and a standard consent form be used. This included a statement requesting participants to authorise the NHS Research and Development be able to access relevant sections of their

medical notes. These changes were made and the study was approved on the 23rd February 2011 (Appendix H).

Finally, the research was also reviewed by NHS Multisite Research and Development team (NHS Permissions CC). This study was approved to be conducted at three NHS sites across Scotland (NHS Highlands, Tayside and Grampian) on the 9th March 2011 (Appendix I).

Power calculation

To ensure that the study had adequate power to detect relationships a power calculation was completed. Previously there was no published research looking at the association between the EDE-Q and either the SMI-1.1 or the CFQ-13. However, literature looking at the relationship between the SMI-1.1 and psychopathology (either axis 1 or 2) found a large effect size (mean Cronbach's α=. 86) Lobbestael *et al,* (2010). Additionally, unpublished research suggests that the CFQ-13 correlates strongly with other measures of psychopathology (such as anxiety and depression). This indicates that both questionnaires will show large effect sizes (Gillanders *et al.*, 2010). Based on this, to have enough power to detect a relationship at α =.05 and β =.8 a minimum of 28 participants will be needed (Cohen, 1992).

Control Group

All questionnaire measures had been designed and validated to differentiate between patients and non patient controls. The main aim of this study was to determine if eating disorder severity was associated with particular schema modes and / or cognitive fusion. For this reason a non-patient control group was not recruited as it was not seen to enhance understanding of eating disorder pathology. Rather a variety of patients from different settings and at different stages of treatment were recruited. This enabled the concept of schema modes and the process of cognitive fusion to be analysed in a wide variety of individuals, some with relatively mild eating disorders symptoms and others very severe.

Design/Statistics

Within subjects Pearson's correlations were used. The independent variable was eating disorder severity (taken from the EDE-Q) and the dependent variables were participants scores on the CFQ-13 and SMI-1.1. Simple mediation analysis and bootstrapping were used to determine if the severity of maladaptive schema modes predicted eating disorder severity independent of cognitive fusion or whether the process of cognitive fusion mediated this relationship to some extent.

Data was then screened to ensure the basic assumptions of regression analysis were met. This included checks of multicollinearity, the use of Durbin-Watson to check whether the residuals in the model were independent and inspection of histograms to ensure normal distribution. As no assumptions were violated Stepwise

regression was conducted to determine which maladaptive schema modes best predicted eating pathology.

Chapter Five

Results

Participants

In total 121 questionnaire packs were given out and 50 invitation letters were posted by clinicians to potential participants. A further proportion of individuals were verbally asked if they would like to participate and declined. In total the response rate was 33 (19%). Two participants were excluded from analysis. One was found to have a learning disability and was unable to complete the majority of the questionnaires. The other did not fully complete the consent form. The distribution of eating disorder diagnoses can be seen in figure 1.

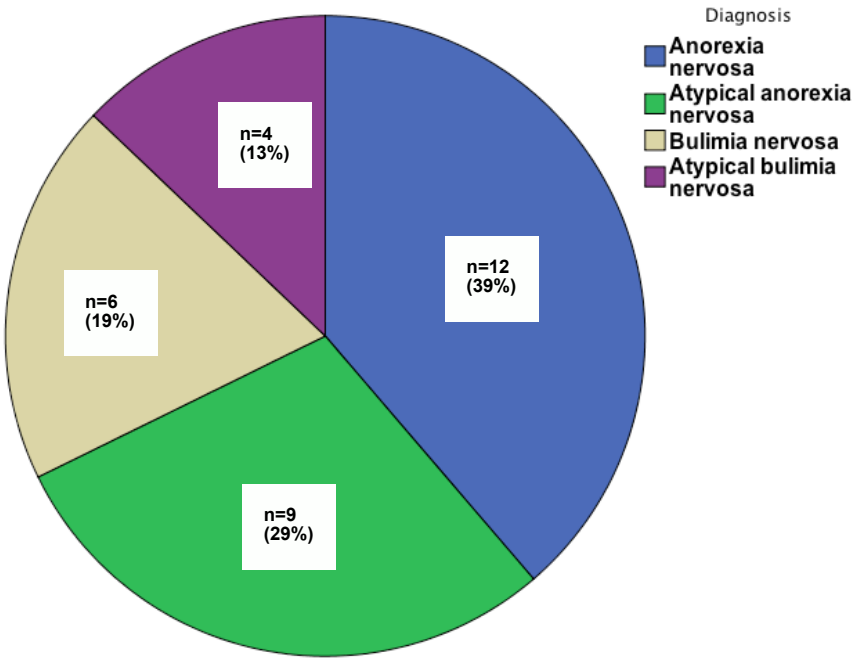


Figure 1. Pie chart to show distribution of eating disorder diagnoses (n=31).

The proportion of participants from outpatient services was 23 (71%) and from inpatient services 10 (29%). Finally, 100% of the participants were female.

Distribution of data

In order to determine if the data were normally distributed histograms were generated to observe the shape of the data (see figures 2, 3 and 4) and kolmogorov-smirnov tests of normality were applied.

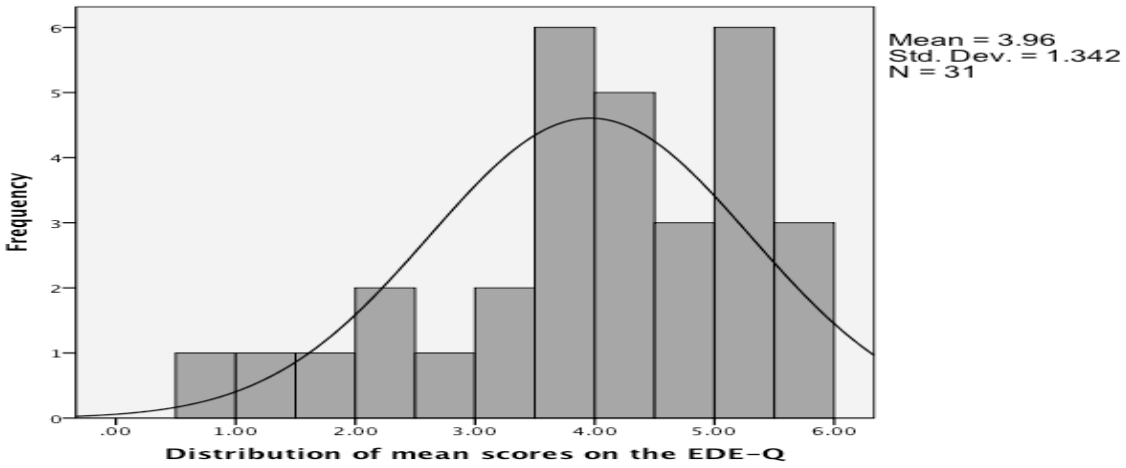


Figure 2. Histogram to show distribution of mean scores on the EDE-Q (*n*=31).

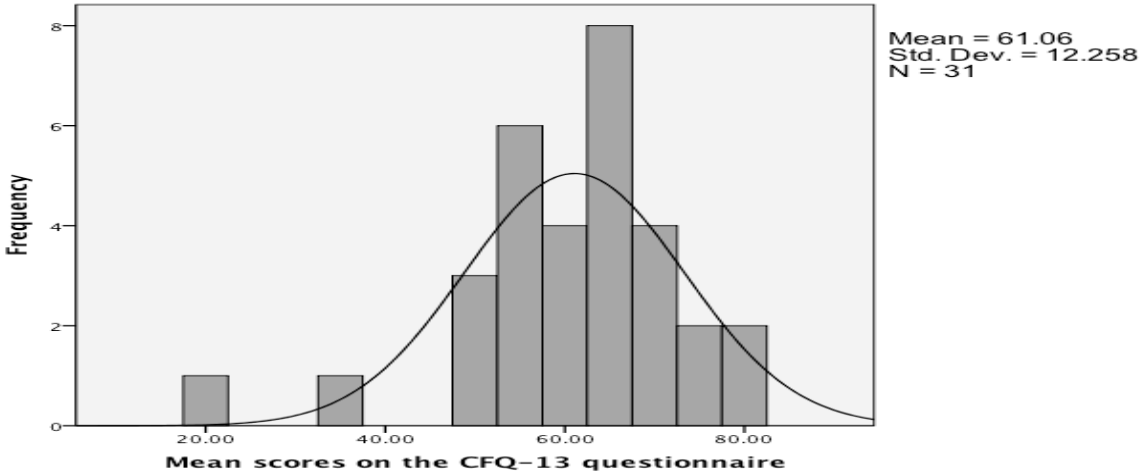


Figure 3. Histogram to show distribution of mean scores on the CFQ-13 (*n*=31).

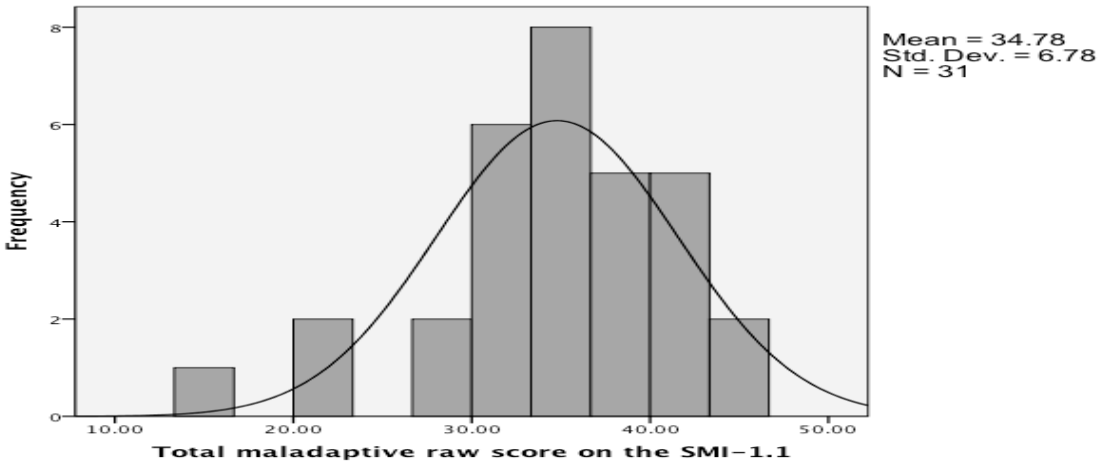


Figure 4. Histogram to show distribution of raw maladaptive schema scores on the SMI-1.1 (*n*=31).

The distributions of the EDE-Q (*D*(31)= 0.13, *p*=.20), CFQ-13 (*D*(31)= 0.15, *p*=.09) and SMI-1.1 (*D*(31)= 0.12, *p*=.20) were not significantly different from normal. This shows the data does not violate the assumptions of normality therefore parametric tests were used.

Descriptive statistics

The mean questionnaire scores can be seen in table 1. The mean maladaptive schema mode scores are displayed alongside the norms found in Lobbestael *et al's* (2008) (table 2). The mean cognitive fusion score is displayed alongside the norms developed by Gillanders *et al*, (2010) (table 3).

Table 1. Maximums, minimums, means and standard deviations on the SMI-1.1, CFQ-13 and the EDE-Q (plus weight concern, shape concern, eating concern and restraint subscales). (*n=31*)

	Max score	**Min score**	**Mean**	**Standard deviation**
EDE-Q Mean score	5.75	0.54	3.95	1.34
EDE-Q Weight concern	6.00	0.60	4.17	1.46
EDE-Q Shape concern	6.00	1.36	4.67	1.45
EDE-Q Eating concern	6.00	0.00	3.53	1.48
EDE-Q Restraint	6.00	0.00	3.40	1.73
Maladaptive SMI-1.1	3.79	1.30	2.91	0.57
CFQ-13	81	20	61	12.26

Table 2. Mean schema mode scores as compared to norms found in Lobbestael et al's., 2008 study.

	Lobbestael et al's 2008 study						Current study	
SMI subscales	Non-patient controls		Axis I patients		Axis II patients		Eating disorder patients	
	m	sd	m	sd	m	sd	m	sd
Vulnerable Child	1.47	.51	2.66	.94	3.36	1.11	3.77	1.03
Angry child	1.81	.48	2.56	.90	3.09	.94	2.47	.09
Enraged Child	1.20	.29	1.55	.67	2.05	.92	1.31	.33
Impulsive Child	2.15	.53	2.46	.72	3.05	.97	2.31	1.04
Undisciplined Child	2.27	.60	2.57	.85	2.95	.94	2.65	.68
Happy Child	4.52	.54	3.39	.87	2.88	.77	2.96	.88
Compliant Surrenderer	2.51	.56	3.00	.88	3.32	.95	3.71	1.04
Detached Protector	1.59	.52	2.35	.94	2.95	.94	2.85	.90
Detached Self-Soother	1.93	.65	3.00	.91	3.32	.98	4.02	.97
Self-Aggrandiser	2.31	.59	2.47	.76	2.63	.87	2.22	.76
Bully and Attack	1.72	.51	1.91	.68	2.21	.77	1.39	.38
Punitive Parent	1.47	.39	2.16	.90	2.75	.97	3.83	1.29
Demanding Parent	3.06	.60	3.50	.85	3.71	.90	4.29	1.05
Healthy Adult	4.60	.56	3.99	.80	3.60	.83	3.59	.90

Table 3. Mean cognitive fusion score as compared to norms found by Gillanders et al, (2010).

	Non Clinical sample (N=893)	Work Stress Sample (N=232)	Mental Health Sample (N=171)	Current Study Eating Disorder Sample (N=31)
Mean (SD)	40.2 (11.04)	47.3 (12.3)	59.7 (12.1)	61 (12.3)

Together these tables show that the eating disorder participants in this study had relatively high levels of eating pathology, maladaptive schema modes and cognitive fusion.

Aim 1. Is there a relationship between schema modes and eating disorder severity?

As can be seen in figure 5, there appears to be a positive linear relationship between schema modes and eating disorder severity. In order to further explore this Pearson's *r* correlation analysis were conducted between each participant's mean maladaptive schema mode score on the SMI-1.1 (the two adaptive modes, the *Happy Child* and *Healthy Adult*, were removed prior to this analysis) and the mean global eating disorder severity score on the EDE-Q.

This demonstrated a positive correlation between these two measures (r=.751, p<. 001) which accounted for 56% of the variance. These results suggest the more severe the eating disorder symptoms the more severe participants' maladaptive schema modes were and vice-versa.

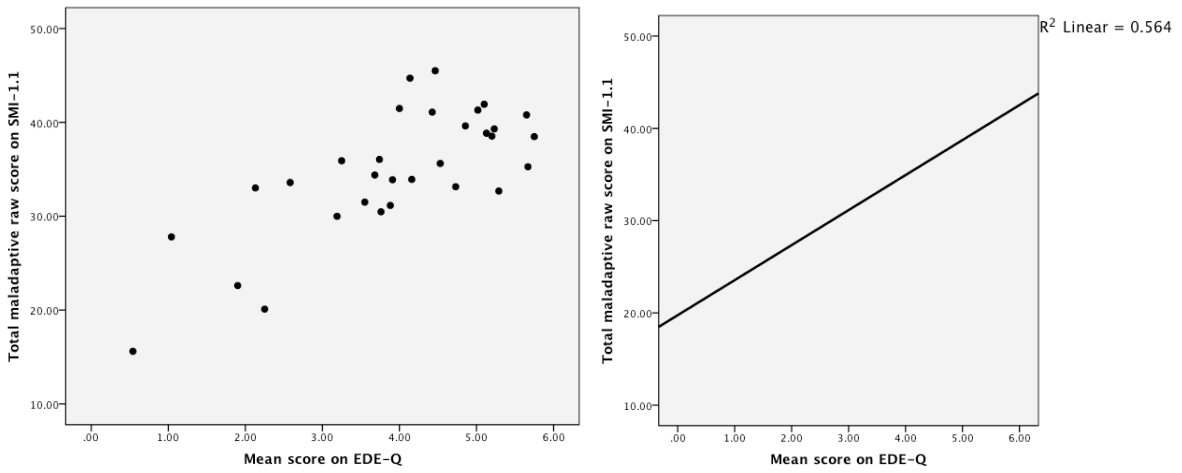


Figure 5. Graph and regression line to show the relationship between participants' scores on the EDE-Q and the SMI-1.1 (*n*=31).

In order to determine if particular schema modes were more associated with eating disorder severity, additional correlation analyses were conducted. These revealed significant correlations between eating disorder severity (EDE-Q global score) and the *Vulnerable Child* mode (*r*=.607, *p*<.001); *Angry Child* mode (*r*=.503, *p*=.004); *Undisciplined Child* mode (*r*=.609, *p*<.001); *Compliant Surrenderer* mode (*r*=.530, *p*=.002); *Detached Self-soother* mode *(r*=.713, *p*<.001); *Self Aggrandise*r mode (*r*=. 460, *p*=.009); *Punitive Parent mode* (*r*=.524, *p*=.002) and the *Demanding Parent* (*r*=. 610, *p*<.001).

In contrast the following modes were **not** significantly associated with eating disorder severity; the *Enraged Child* (*r*=.322, *p*=.078), *Impulsive Child* (*r*=.246, *p*=.182), *Happy Child* (*r*=-.176, *p*=.345), *Detached Protector* (*r*=.246, *p*=.183), *Bully and Attack* (*r*=.043, *p*=.820) and the *Healthy Adult* mode (*r*=-.198, *p*=.284).

These results demonstrate some specificity in the relationship between eating disorder severity and schema modes. Finally, although the *Detached Protector* mode was not correlated with eating disorder severity, it was still similar to the mean

axis II norms found in Lobbestael *et al's*, (2008) study. This suggests that it was relatively severe in this sample but that it did not increase in relation to eating disorder severity.

In order to determine which of the schema modes were most predictive of eating disorder severity stepwise regression was conducted. Overall this model demonstrated that the *Detached Self-Soother* ($t(30)= 4.27$, standardised $b=.55$, $p<.001$) and the *Vulnerable Child* ($t(30)= 2.83$, standardised $b= .37$, $p=.009$) modes were the most predictive of eating disorder severity. This relationship is positive suggesting that the more severe the *Detached Self-Soother* and *Vulnerable Child* the more severe the eating disorder.

Is there a relationship between specific subscales on the EDE-Q and schema modes?

The EDE-Q has four subscales; weight concern, restraint, eating concern and shape concern. In order to explore whether specific schema modes were associated with any of these subscales, additional two tailed Pearson's correlations were conducted. Due to the number of correlations being performed a more stringent *p* value was used ($p<.01$) to reduce the chance of making a type 1 error. The results can be seen in table 4.

Table 4. Pearson's correlation for association between schema modes and EDE-Q subscales (*n*=31)

	Weight Concern	Shape Concern	Eating Concern	Restraint
Vulnerable Child	**.618****	**.705****	**.440***	**.441***
Angry Child	**.598****	**.533***	0.358	0.421
Enraged Child	0.370	0.201	0.285	0.362
Impulsive Child	0.326	0.262	0.182	0.219
Undisciplined Child	**.583****	**.697****	**.518***	**.529***
Happy Child	-0.155	-0.258	-0.053	-0.093
Compliant Surrenderer	**.456***	**.578****	0.345	**.544***
Detached Protector	0.215	0.343	0.226	0.085
Detached Self-Soother	**.699****	**.571****	**.633****	**.661****
Self-Aggrandiser	0.349	0.308	**.464***	**.573****
Bully and Attack	-0.015	0.066	0.058	0.117
Punitive Parent	**.539***	**.705****	0.364	0.383
Demanding Parent	**.539***	**.538***	**.550****	**.621****
Healthy Adult	-0.247	-0.360	-0.086	-0.066

***p<.01, **p<.001**

Aim 2. Is there a relationship between cognitive fusion and eating disorder severity?

As can be seen in figure 6, there appears to be a positive linear relationship between cognitive fusion and eating disorder severity. In order to further explore this, Pearson's *r* correlation analyses were conducted between each participant's mean global score on the EDE-Q and the CFQ-13. This demonstrated a positive correlation between these two measures (r=.706, p<.001), which accounted for 50% of the variance. These results suggest that the more severe the eating disorder

symptoms the higher participants' scores were on the CFQ-13. These results demonstrate that as fusion and entanglement with thinking increases, so does eating pathology and vice versa.

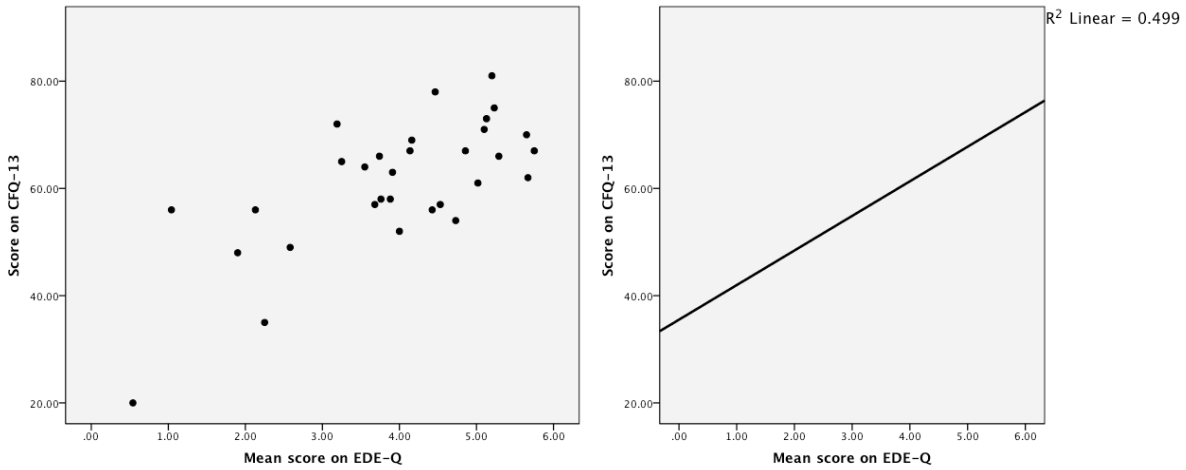


Figure 6. Graph and regression line to show the relationship between participants' scores on the EDE-Q and the CFQ-13 (*n*=31).

Exploratory analyses

Is there a relationship between participants' scores on the SMI-1.1 and the CFQ-13?

As can be seen in figure 7, there appears to be a positive linear relationship between the CFQ-13 and the SMI-1.1. In order to further explore this Pearson's *r* correlation analyses were conducted between each participant's raw maladaptive schema mode score on the SMI-1.1 and the CFQ-13. This demonstrated a positive correlation between these two measures (r=.747, p<.001), which accounted for 56% of the variance. These results demonstrate that as fusion and entanglement with thinking increases, so does the severity of participants' maladaptive schema modes and vice versa.

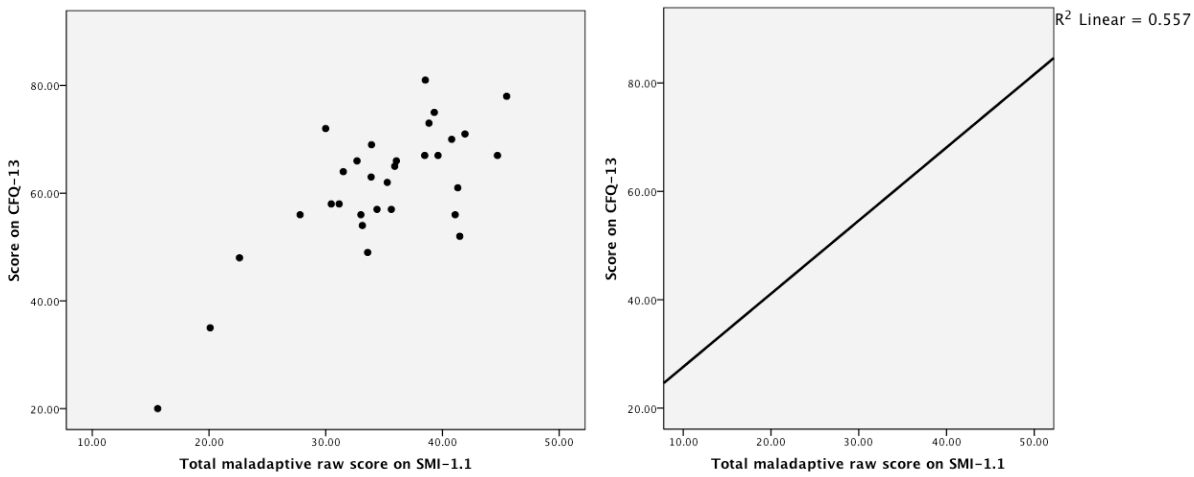


Figure 7. Graph and regression line to show the relationship between participants' scores on the SMI-1.1 and the CFQ-13 (*n*=31).

In order to determine if particular schema modes were more highly correlated with participants' scores on the CFQ-13 additional correlation analyses were conducted. These revealed significant correlations between cognitive fusion and the *Vulnerable Child* mode (*r*=.500, *p*=.004); *Angry Child* mode (*r*=.523, *p*=.003); *Enraged Child* mode (*r*=.480, *p*=.006); *Impulsive Child* mode (*r*=.399, *p*=.026); *Undisciplined Child* mode (*r*=.659, *p*<.001); *Compliant Surrenderer* mode (*r*=.392, *p*=.029); *Detached Self-soother* mode *(r*=.681, *p*<.001); *Self Aggrandiser* mode (*r*=.360, *p*=.047); *Punitive Parent mode* (*r*=.557, *p*=.001) and the *Demanding Parent* (*r*=.593, *p*<.001).

In contrast, the following modes were **not** correlated with cognitive fusion; the *Happy Child* (*r*=-.104, *p*=.579), *Detached Protector* (*r*=.184, *p*=.323), *Bully and Attack* (*r*=. 157, *p*=.398) and the *Healthy Adult* mode (*r*=-.145, *p*=.436). Again these results demonstrate some specificity in the relationship between schema mode severity and cognitive fusion.

Can we make any predictions based on these results?

To date the above results demonstrate that both cognitive fusion and maladaptive schema modes are associated with eating disorder severity. However, simple correlation analysis cannot determine causality. Neither can it determine whether one of the independent variables mediates (or accounts for some of the relationship) between the other and eating disorder severity. Deeper understanding is gained by attempting to understand the processes that underlie these relationships.

In order to look in greater detail at these potential processes, regression analysis was used. As the two predictor variables (maladaptive schema modes and cognitive fusion) appeared to share a large amount of variance (Figure 7) a form of regression called mediation analysis was chosen. This allowed for exploration of whether one variable (cognitive fusion) mediated the relationship between the other variable (maladaptive schema modes) and eating disorder severity.

Various guidance is given on the number of participants needed to undertake regression analysis. Old 'rules of thumb' recommended 10 or 15 participants per predictor variable (Field, 2009). Based on these old rules of thumb the current study needed between 20-30 participants to conduct this analysis. Recently these rules of thumb have been widely criticised for being over-simplistic. In order to determine the sample size it is now believed to be important to consider the size of the expected effect (is it small, medium or large) and the power needed to detect this effect. Therefore, in order to have enough power to conduct a regression analysis with two predictor variables, an expected large effect size, with power=.80 and an alpha of . 05, the current study would require a minimum of 30 participants (Green, 1991, table 1, p.505).

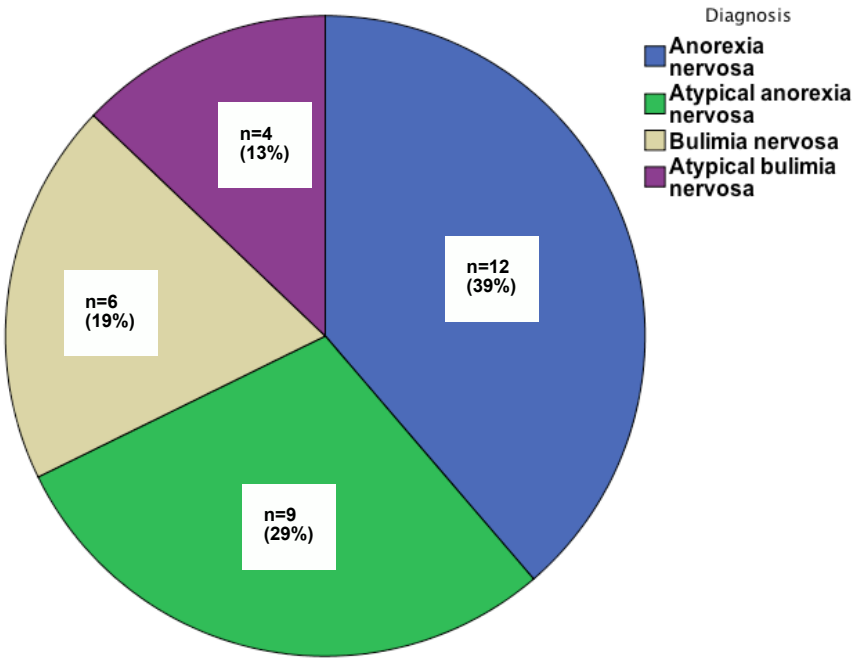
In order to determine whether schema modes predicted eating disorder severity independent of cognitive fusion or whether the process of cognitive fusion mediated this relationship, Bootstrapping was used. Results of the indirect effect, based on a bootstrapped sample of *n* = 5,000, revealed that zero was contained within the lower and upper limits (*BC* lower = -49.47, *BC* upper = 0.88), thus indicating that cognitive fusion did not mediate the relationship between schema modes and eating disorder severity when using this method.

Chapter Five

Results

Participants

In total 121 questionnaire packs were given out and 50 invitation letters were posted by clinicians to potential participants. A further proportion of individuals were verbally asked if they would like to participate and declined. In total the response rate was 33 (19%). Two participants were excluded from analysis. One was found to have a learning disability and was unable to complete the majority of the questionnaires. The other did not fully complete the consent form. The distribution of eating disorder diagnoses can be seen in figure 1.



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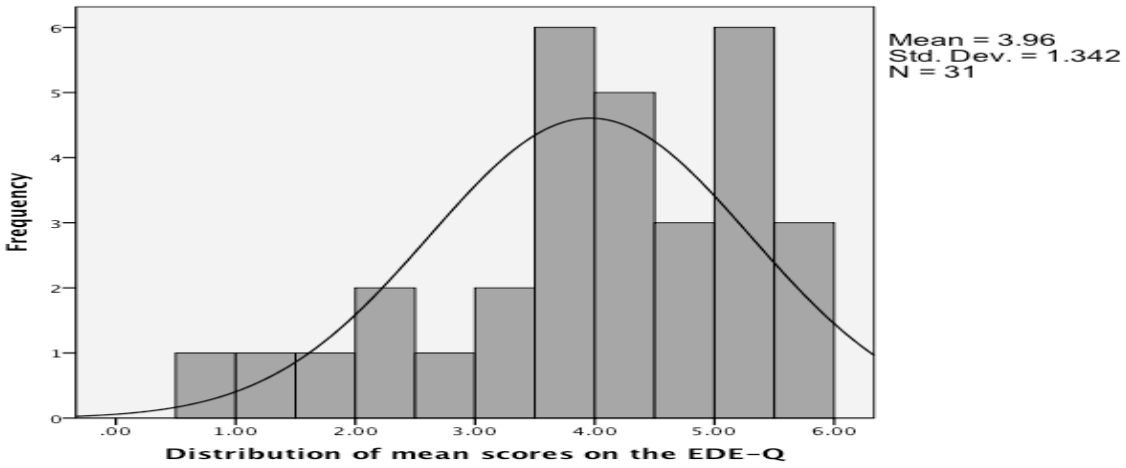
In order to determine if the data were normally distributed histograms were generated to observe the shape of the data (see figures 2, 3 and 4) and kolmogorov-smirnov tests of normality were applied.



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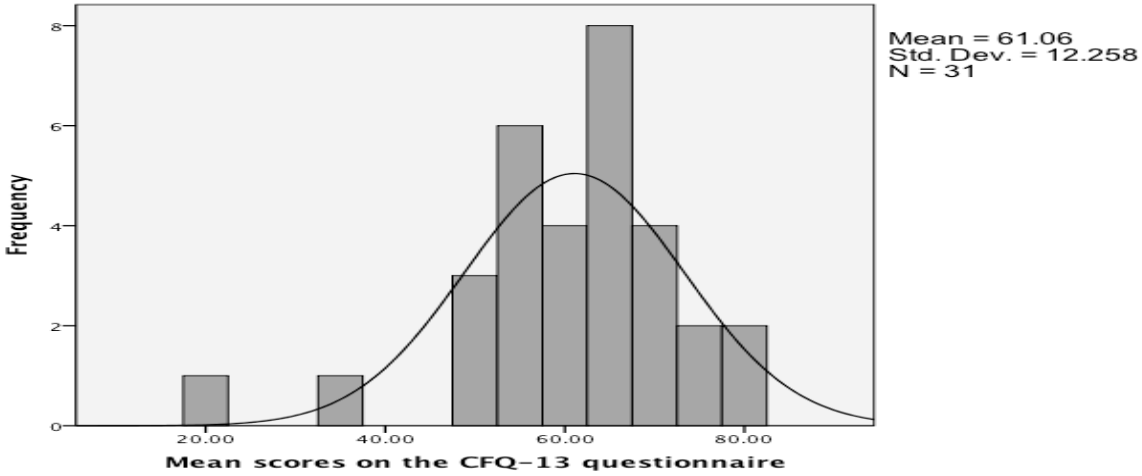
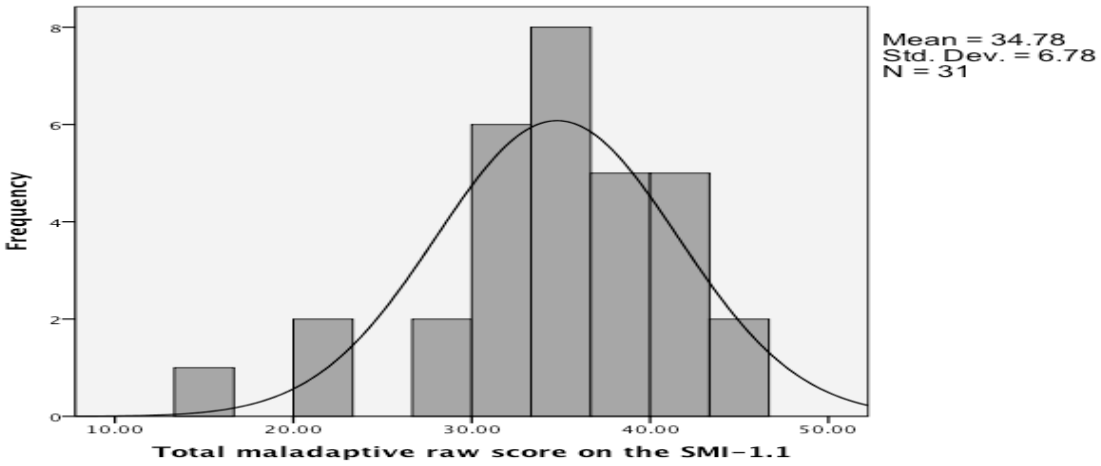


Figure 3. Histogram to show distribution of mean scores on the CFQ-13 (*n*=31).



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The distributions of the EDE-Q (*D*(31)= 0.13, *p*=.20), CFQ-13 (*D*(31)= 0.15, *p*=.09) and SMI-1.1 (*D*(31)= 0.12, *p*=.20) were not significantly different from normal. This shows the data does not violate the assumptions of normality therefore parametric tests were used.

Descriptive statistics

The mean questionnaire scores can be seen in table 1. The mean maladaptive schema mode scores are displayed alongside the norms found in Lobbestael *et al's* (2008) (table 2). The mean cognitive fusion score is displayed alongside the norms developed by Gillanders *et al*, (2010) (table 3).

Table 1. Maximums, minimums, means and standard deviations on the SMI-1.1, CFQ-13 and the EDE-Q (plus weight concern, shape concern, eating concern and restraint subscales). (*n=31*)

	Max score	**Min score**	**Mean**	**Standard deviation**
EDE-Q Mean score	5.75	0.54	3.95	1.34
EDE-Q Weight concern	6.00	0.60	4.17	1.46
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EDE-Q Restraint	6.00	0.00	3.40	1.73
Maladaptive SMI-1.1	3.79	1.30	2.91	0.57
CFQ-13	81	20	61	12.26

Table 2. Mean schema mode scores as compared to norms found in Lobbestael et al's., 2008 study.

	Lobbestael et al's 2008 study						Current study	
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Vulnerable Child	1.47	.51	2.66	.94	3.36	1.11	3.77	1.03
Angry child	1.81	.48	2.56	.90	3.09	.94	2.47	.09
Enraged Child	1.20	.29	1.55	.67	2.05	.92	1.31	.33
Impulsive Child	2.15	.53	2.46	.72	3.05	.97	2.31	1.04
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Happy Child	4.52	.54	3.39	.87	2.88	.77	2.96	.88
Compliant Surrenderer	2.51	.56	3.00	.88	3.32	.95	3.71	1.04
Detached Protector	1.59	.52	2.35	.94	2.95	.94	2.85	.90
Detached Self-Soother	1.93	.65	3.00	.91	3.32	.98	4.02	.97
Self-Aggrandiser	2.31	.59	2.47	.76	2.63	.87	2.22	.76
Bully and Attack	1.72	.51	1.91	.68	2.21	.77	1.39	.38
Punitive Parent	1.47	.39	2.16	.90	2.75	.97	3.83	1.29
Demanding Parent	3.06	.60	3.50	.85	3.71	.90	4.29	1.05
Healthy Adult	4.60	.56	3.99	.80	3.60	.83	3.59	.90

Table 3. Mean cognitive fusion score as compared to norms found by Gillanders et al, (2010).

	Non Clinical sample (N=893)	Work Stress Sample (N=232)	Mental Health Sample (N=171)	Current Study Eating Disorder Sample (N=31)
Mean (SD)	40.2 (11.04)	47.3 (12.3)	59.7 (12.1)	61 (12.3)

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This demonstrated a positive correlation between these two measures (r=.751, p<. 001) which accounted for 56% of the variance. These results suggest the more severe the eating disorder symptoms the more severe participants' maladaptive schema modes were and vice-versa.

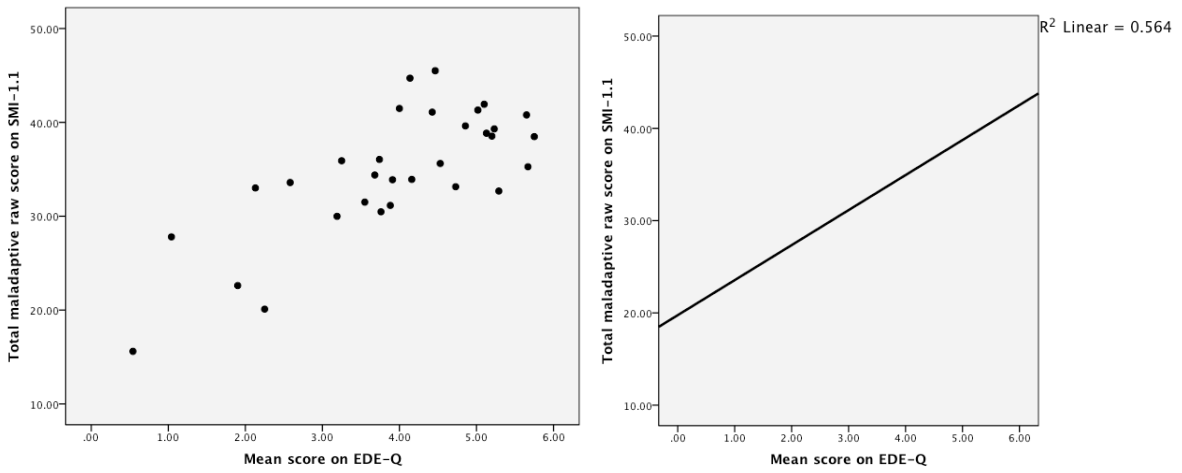

Figure 5. Graph and regression line to show the relationship between participants' scores on the EDE-Q and the SMI-1.1 (*n*=31).

In order to determine if particular schema modes were more associated with eating disorder severity, additional correlation analyses were conducted. These revealed significant correlations between eating disorder severity (EDE-Q global score) and the *Vulnerable Child* mode (*r*=.607, *p*<.001); *Angry Child* mode (*r*=.503, *p*=.004); *Undisciplined Child* mode (*r*=.609, *p*<.001); *Compliant Surrenderer* mode (*r*=.530, *p*=.002); *Detached Self-soother* mode *(r*=.713, *p*<.001); *Self Aggrandise*r mode (*r*=. 460, *p*=.009); *Punitive Parent mode* (*r*=.524, *p*=.002) and the *Demanding Parent* (*r*=. 610, *p*<.001).

In contrast the following modes were **not** significantly associated with eating disorder severity; the *Enraged Child* (*r*=.322, *p*=.078), *Impulsive Child* (*r*=.246, *p*=.182), *Happy Child* (*r*=-.176, *p*=.345), *Detached Protector* (*r*=.246, *p*=.183), *Bully and Attack* (*r*=.043, *p*=.820) and the *Healthy Adult* mode (*r*=-.198, *p*=.284).

These results demonstrate some specificity in the relationship between eating disorder severity and schema modes. Finally, although the *Detached Protector* mode was not correlated with eating disorder severity, it was still similar to the mean

axis II norms found in Lobbestael *et al's*, (2008) study. This suggests that it was relatively severe in this sample but that it did not increase in relation to eating disorder severity.

In order to determine which of the schema modes were most predictive of eating disorder severity stepwise regression was conducted. Overall this model demonstrated that the *Detached Self-Soother* ($t(30)= 4.27$, standardised $b=.55$, $p<.001$) and the *Vulnerable Child* ($t(30)= 2.83$, standardised $b= .37$, $p=.009$) modes were the most predictive of eating disorder severity. This relationship is positive suggesting that the more severe the *Detached Self-Soother* and *Vulnerable Child* the more severe the eating disorder.

Is there a relationship between specific subscales on the EDE-Q and schema modes?

The EDE-Q has four subscales; weight concern, restraint, eating concern and shape concern. In order to explore whether specific schema modes were associated with any of these subscales, additional two tailed Pearson's correlations were conducted. Due to the number of correlations being performed a more stringent *p* value was used ($p<.01$) to reduce the chance of making a type 1 error. The results can be seen in table 4.

Table 4. Pearson's correlation for association between schema modes and EDE-Q subscales (*n*=31)

	Weight Concern	Shape Concern	Eating Concern	Restraint
Vulnerable Child	**.618****	**.705****	**.440***	**.441***
Angry Child	**.598****	**.533***	0.358	0.421
Enraged Child	0.370	0.201	0.285	0.362
Impulsive Child	0.326	0.262	0.182	0.219
Undisciplined Child	**.583****	**.697****	**.518***	**.529***
Happy Child	-0.155	-0.258	-0.053	-0.093
Compliant Surrenderer	**.456***	**.578****	0.345	**.544***
Detached Protector	0.215	0.343	0.226	0.085
Detached Self-Soother	**.699****	**.571****	**.633****	**.661****
Self-Aggrandiser	0.349	0.308	**.464***	**.573****
Bully and Attack	-0.015	0.066	0.058	0.117
Punitive Parent	**.539***	**.705****	0.364	0.383
Demanding Parent	**.539***	**.538***	**.550****	**.621****
Healthy Adult	-0.247	-0.360	-0.086	-0.066

***p<.01, **p<.001**

Aim 2. Is there a relationship between cognitive fusion and eating disorder severity?

As can be seen in figure 6, there appears to be a positive linear relationship between cognitive fusion and eating disorder severity. In order to further explore this, Pearson's *r* correlation analyses were conducted between each participant's mean global score on the EDE-Q and the CFQ-13. This demonstrated a positive correlation between these two measures (r=.706, p<.001), which accounted for 50% of the variance. These results suggest that the more severe the eating disorder

symptoms the higher participants' scores were on the CFQ-13. These results demonstrate that as fusion and entanglement with thinking increases, so does eating pathology and vice versa.

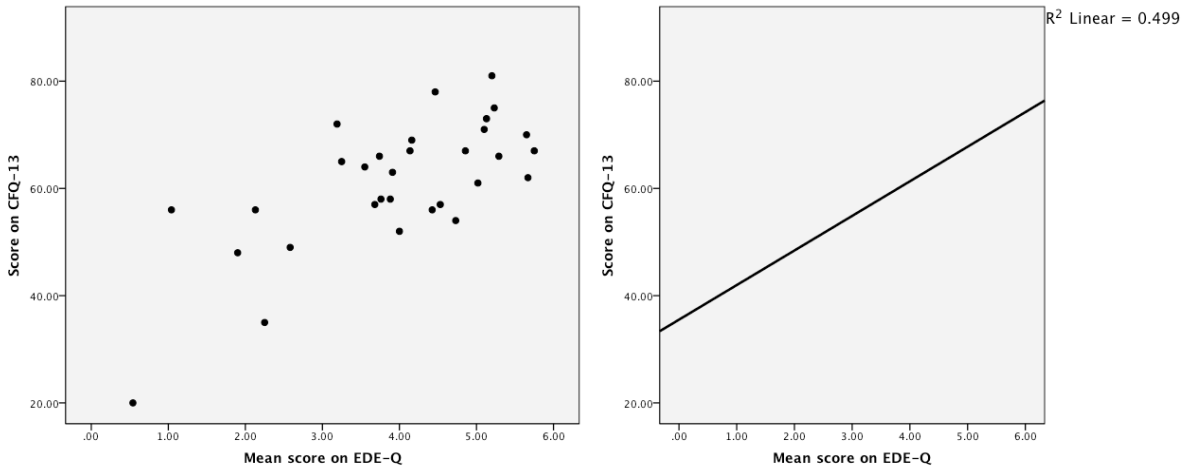

Figure 6. Graph and regression line to show the relationship between participants' scores on the EDE-Q and the CFQ-13 (*n*=31).

Exploratory analyses

Is there a relationship between participants' scores on the SMI-1.1 and the CFQ-13?

As can be seen in figure 7, there appears to be a positive linear relationship between the CFQ-13 and the SMI-1.1. In order to further explore this Pearson's *r* correlation analyses were conducted between each participant's raw maladaptive schema mode score on the SMI-1.1 and the CFQ-13. This demonstrated a positive correlation between these two measures (r=.747, p<.001), which accounted for 56% of the variance. These results demonstrate that as fusion and entanglement with thinking increases, so does the severity of participants' maladaptive schema modes and vice versa.

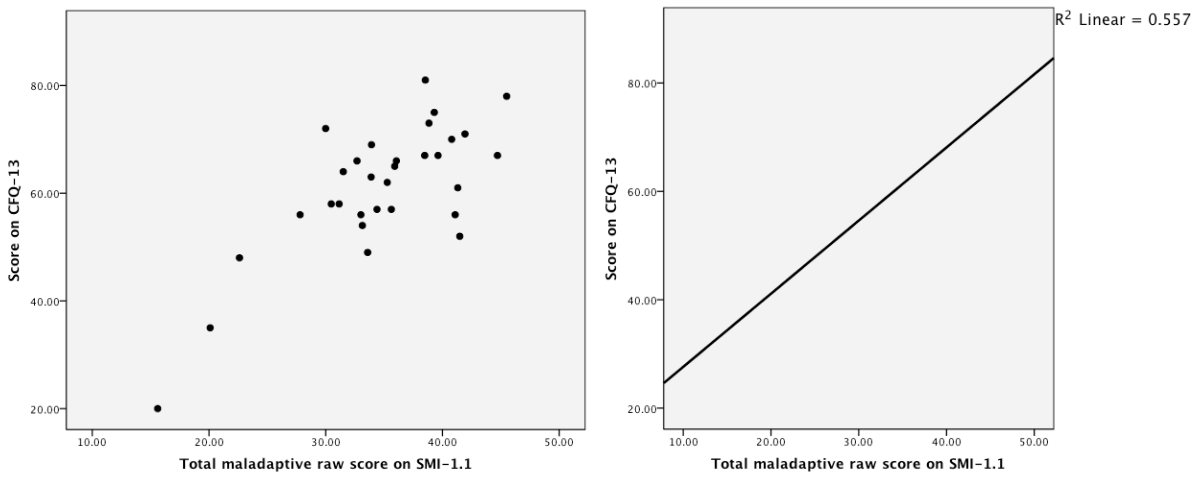

Figure 7. Graph and regression line to show the relationship between participants' scores on the SMI-1.1 and the CFQ-13 (*n*=31).

In order to determine if particular schema modes were more highly correlated with participants' scores on the CFQ-13 additional correlation analyses were conducted. These revealed significant correlations between cognitive fusion and the *Vulnerable Child* mode (*r*=.500, *p*=.004); *Angry Child* mode (*r*=.523, *p*=.003); *Enraged Child* mode (*r*=.480, *p*=.006); *Impulsive Child* mode (*r*=.399, *p*=.026); *Undisciplined Child* mode (*r*=.659, *p*<.001); *Compliant Surrenderer* mode (*r*=.392, *p*=.029); *Detached Self-soother* mode *(r*=.681, *p*<.001); *Self Aggrandiser* mode (*r*=.360, *p*=.047); *Punitive Parent mode* (*r*=.557, *p*=.001) and the *Demanding Parent* (*r*=.593, *p*<.001).

In contrast, the following modes were **not** correlated with cognitive fusion; the *Happy Child* (*r*=-.104, *p*=.579), *Detached Protector* (*r*=.184, *p*=.323), *Bully and Attack* (*r*=. 157, *p*=.398) and the *Healthy Adult* mode (*r*=-.145, *p*=.436). Again these results demonstrate some specificity in the relationship between schema mode severity and cognitive fusion.

Can we make any predictions based on these results?

To date the above results demonstrate that both cognitive fusion and maladaptive schema modes are associated with eating disorder severity. However, simple correlation analysis cannot determine causality. Neither can it determine whether one of the independent variables mediates (or accounts for some of the relationship) between the other and eating disorder severity. Deeper understanding is gained by attempting to understand the processes that underlie these relationships.

In order to look in greater detail at these potential processes, regression analysis was used. As the two predictor variables (maladaptive schema modes and cognitive fusion) appeared to share a large amount of variance (Figure 7) a form of regression called mediation analysis was chosen. This allowed for exploration of whether one variable (cognitive fusion) mediated the relationship between the other variable (maladaptive schema modes) and eating disorder severity.

Various guidance is given on the number of participants needed to undertake regression analysis. Old 'rules of thumb' recommended 10 or 15 participants per predictor variable (Field, 2009). Based on these old rules of thumb the current study needed between 20-30 participants to conduct this analysis. Recently these rules of thumb have been widely criticised for being over-simplistic. In order to determine the sample size it is now believed to be important to consider the size of the expected effect (is it small, medium or large) and the power needed to detect this effect. Therefore, in order to have enough power to conduct a regression analysis with two predictor variables, an expected large effect size, with power=.80 and an alpha of . 05, the current study would require a minimum of 30 participants (Green, 1991, table 1, p.505).

In order to determine whether schema modes predicted eating disorder severity independent of cognitive fusion or whether the process of cognitive fusion mediated this relationship, Bootstrapping was used. Results of the indirect effect, based on a bootstrapped sample of *n* = 5,000, revealed that zero was contained within the lower and upper limits (*BC* lower = -49.47, *BC* upper = 0.88), thus indicating that cognitive fusion did not mediate the relationship between schema modes and eating disorder severity when using this method.

Chapter Seven

Journal article

Exploring the Relationship Between Schema Modes, Cognitive Fusion and Eating Disorders

Written for the International Journal of Eating Disorders. See appendix J for author instructions.

For presentation purposes, tables and figures have been left in the main body of text, paragraphs have been separated rather than indented and all text has been justified. This is for continuity of presentation for University of Edinburgh submission.

Abstract

Objective: Due to the limited efficacy of psychological therapies for individuals with eating disorders the evidence base for psychological therapies needs to be developed in order to meet the high levels of need, complexity and co-morbidity in this population. This project is interested in exploring how psychological constructs from Schema Therapy (schema modes) and psychological processes from Acceptance and Commitment Therapy (cognitive fusion) function in the context of eating disorder severity.

Method: Thirty-one participants with an eating disorder completed measures of eating disorder severity, schema modes and cognitive fusion. Data was analysed using within subjects Pearson's correlations and simple mediation analyses.

Results: Eating disorder severity was significantly associated with both maladaptive schema modes and cognitive fusion. This demonstrates that higher eating disorder severity is linked to more severe schema modes and cognitive fusion. Finally, mediation analyses demonstrated that the total effects of maladaptive schema modes and cognitive fusion were associated with eating disorder severity but that independently neither variable was a clear predictor of eating pathology.

Discussion: This study demonstrates that both the construct of schema modes and the process of cognitive fusion may contribute to our understanding of eating disorders and that both models warrant further exploration.

Introduction

Integral to the role of clinical psychologists working within health care settings is ensuring that they are providing evidence based treatments and interventions. In the field of eating disorders, the evidence base for effective psychological treatments is relatively poor[1,2]. This is despite eating disorders being severe, disabling and relatively common[3,4,5,6,7].

Overall, the treatment of choice for Bulimia Nervosa (BN) is cognitive behaviour therapy (CBT). The evidence base for other eating disorders and co-morbidity between eating disorders and other Axis I and II disorders is lacking[8,9]. Despite CBT been the most recommended treatment for eating disorders, a relatively large subset of individuals do not achieve any clinically significant benefit from CBT[10]. In fact some studies demonstrate only 30-50% of patients cease to binge and purge using this approach[11,12,13]. The outcomes for Anorexia Nervosa (AN) have been even less encouraging[12,2]. These findings suggest that although CBT may benefit some individuals there is still a large proportion of individuals whose needs have not been adequately met.

There are a number of reasons why CBT might not be best suited to treat eating disorders. Firstly, patients with eating pathology (particularly those with AN) might have little desire to change[10]. The eating disorder may be viewed as something that has helped them to lose weight which might be a valued achievement[14]. This may undermine the basic principle of collaboration which is essential to CBT. Secondly, CBT directly attempts to change the content of unhelpful eating-related cognitions.

The nature of eating disorder cognitions may make them particularly resistant to direct modification efforts. In particular, difficulties set-shifting[15] and cognitive rigidity may be symptoms of the eating disorder which may make cognitive challenging particularly difficult[16]. Thirdly, many eating disorders may be functional within the context of the patient's belief system[10]. An example would be when someone (erroneously) believes they are overweight and thus finds eating pathology assists them in weight reduction.

In order to improve outcomes for individuals with an eating disorder it is important to develop our understanding of eating disorders and potentially explore new treatment models and approaches. The primary aim of this research is to explore whether two relatively new therapeutic models; schema therapy (ST)[17] and acceptance and commitment therapy (ACT)[18] may enhance our understanding of eating disorders.

Theoretical and empirical evidence for these therapies in an eating disorder population are still in their infancy. In relation to ST, Leung *et al.*[19] demonstrated that women with eating disorders held more dysfunctional schemas than a control group. Additionally, different patterns of schemas were observed in AN and BN suggesting that particular schemas may be associated with particular eating behaviours[19]. Although Leung *et al.*[19] were the first to propose a link between eating disorders and early maladaptive schemas, this relationship has since been supported by Waller *et al.*[20,21] who demonstrated that certain schemas were predictive of levels of eating disordered behaviour.

The most recent hypothesis put forward by Waller[22] is that restrictive and bulimic pathologies are both related to affect regulation. The key difference between anorexic and bulimic pathologies is the point at which the individual makes an attempt to reduce the experience of intolerable negative affect[22]. In restrictive pathology the individual is hypothesised to use primary avoidance strategies and subsequently may attempt to avoid negative affect being triggered at all. In bulimic pathology it is hypothesised that the individual may use secondary avoidance strategies which attempt to reduce affect that has already been triggered[22].

Waller's hypothesis that eating disorder symptoms may be related to affect regulation suggests that eating pathology (whatever the symptoms) may share a similar function. This potential commonality between eating pathology is supported by various research into the transdiagnostic theory of eating disorders[47]. This model suggests that although different eating disorder diagnoses share distinct psychopathology they also have various similarities[47]. This alternative transdiagnostic view of eating pathology may explain why some eating disordered patients move between diagnostic categories over time[48]. The transdiagnostic model could be seen as a radical new way of thinking that has a number of implications for the assessment and treatment of eating disorders. It represents a shift away from the diagnostic model and instead focuses on the underlying function of the eating disorder (for example affect regulation)[48]. Given the poor outcomes of traditional diagnostic approaches to conceptualisation and intervention this research aims to recruit a mixed diagnosis sample in line with the transdiagnostic model of eating disorders.

A recent review of the evidence base for ST[23] found only one study that has applied ST to individuals who had an eating disorder[24]. In this study, the effectiveness of group ST was empirically tested in an outpatient eating disorder service. Overall, the ST group resulted in reductions of eating disorder severity, anxiety and shame whilst quality of life increased. These benefits resulted in large effect sizes at a six month follow up. The benefits of this pilot study demonstrate that further research is needed into the potential benefits of using ST in the treatment of eating disorders[24].

Schema modes are the most recent addition to the ST model. Modes reflect the moment-to-moment emotional and behavioural state of a person at a given time. Modes comprise of clusters of schemas, for example, *defectiveness* (the belief that one is flawed or defective) and *emotional deprivation* (the belief that you will never be understood and that your needs will never be met by others) are both part of the *lonely child mode*. ST and schema mode therapy do not reflect two separate entities, rather schema mode work is seen as an advanced component of ST which is particularly beneficial when working with individuals who have borderline personality disorder or other complex presentations. Such individuals often present with a number of schemas being simultaneously activated, which can make individual schema work more complex[17]. By allowing therapists to work with groups of schemas simultaneously, schema mode therapy can simplify therapeutic interventions for some individuals.

Finally, although no published study has explored the relationship between eating disorders and schema modes, previous unpublished research looked at whether

schema modes differed between a clinical and control population[25]. This research supported Waller's[22] hypothesis that the coping modes (*Detached Protector, Detached Self-Soother* and the *Compliant Surrenderer*) were characteristic modes in an eating disorder population. Additionally, higher levels of the *Vulnerable Child* mode was also associated with eating disorders[25]. Although this research was able to demonstrate that schema modes were more prevalent in an eating disorder population, it failed to look at the relationship between eating disorder severity and schema modes. This will be a primary aim of this study.

Conceptualisation of eating disorders from an ACT perspective would state that the eating disorder serves a function to the individual[26]. This function is commonly to avoid difficult uncontrollable emotions[26,27,28]. Psychological flexibility and cognitive fusion are often associated with non-acceptance of emotion and experiential avoidance. Cognitive fusion has been described as the process by which thoughts about an event become fused with the actual event and as the excessive attachment to the literal content of thought that makes healthy psychological flexibility difficult or impossible (Hayes, 2004). Therefore individuals with high cognitive fusion are more likely to fuse themselves and their identity with their language system and experience.

When an individual has used language in a way that appraises feelings of depression, anxiety and pain as wrong, experiential avoidance is more likely to occur. Experiential avoidance is anything the individual does to avoid being in contact with a distressing aspect of a private experience (e.g. anxiety). Based on this assumption, individuals may try to avoid some experiences altogether which

starts to limit the activities an individual will engage in. Cognitive fusion alone is unlikely to generate psychopathology but when it is associated with avoidance strategies it starts to become problematic.

It is anticipated that individuals with high levels of cognitive fusion will have poor psychological flexibility and psychological inflexibility is associated with the development and maintenance of psychopathology. This study will assess if eating disorder severity is associated with high levels of cognitive fusion. Again, if theoretical links are found this provides rationale to continue on to conduct clinical trials assessing the treatment effectiveness of the model within eating disorder populations. This link has been supported in the field of eating disorders by various researchers who have found that acceptance, greater psychological flexibility and mindfulness are associated with better treatment outcomes for individuals who have an eating disorder[10,29,30]. Conversely, non-acceptance of emotional experience has been associated with dietary restraint[31] and rigid inflexible beliefs with body dissatisfaction and disordered eating[32].

Empirical support for ACT within an eating disorder population comes from the study by Juarascio, Forman & Herbert[10] who looked at whether ACT or traditional CBT would be more effective in treating eating disorders. Overall, ACT (pre to post-treatment Cohen's d = 1.89) was shown to be superior to CBT (d =0.48) at reducing problem eating behavior[10]. Another study looked at the role of interoceptive awareness in eating disorders[31]. Interestingly this study found evidence to suggest that negative reactions (such as non-acceptance) to emotional responses may contribute to dietary restraint[31]. ACT has also been shown to be helpful both with

weight related self-stigma and weight maintenance[33,30], body image dissatisfaction and disordered eating[32] and has been applied in case studies to those with eating disorders[34]. Most recently, ACT has also been shown to improve eating attitudes, reduce body anxiety and reduce preoccupation with weight and shape[26].

At its core ACT attempts to promote acceptance of emotional responses and internal experiences thus potentially increasing the viability of this model for working with individuals with eating disorders. Although different therapeutic techniques maybe employed, ST would also seek to understand how an individual copes with emotional experience and would seek to challenge maladaptive coping strategies and the core schemas and modes thought to drive these experiences.

Rationale for current study

Due to the limited efficacy of psychological therapies for individuals with eating disorders the evidence base needs to be developed further so that psychological therapies can better meet the needs of the eating disorder population. This project is interested in exploring how psychological constructs from ST (schema modes) and psychological processes from ACT (cognitive fusion) relate to eating disorder severity.

Additionally, as verbal processes are an integral feature of schema modes, it is anticipated that the process of cognitive fusion will influence the relationship between schema modes and eating disorder severity. This hypothesis is based on the assumption that high levels of cognitive fusion will influence an individuals experience of the negative cognitive content associated with maladaptive schema

modes. This may then result in the cognitive element of schema modes inducing greater levels of distress in individuals who have higher levels of cognitive fusion. Intuitively, if the eating disorder symptoms are functioning to manage emotional experiences then it can be hypothesised that the process of cognitive fusion may mediate the relationship between schema modes and eating disorder severity.

To explore this hypothesis a form of regression called mediation analysis will be used. Although there are various mediation models to choose from Bootstrapping is a non-parametric approach to effect-size estimation and hypothesis testing that makes no assumptions about the shape of the distributions[49]. Due to the anticipated sample size being relatively small for regression analysis this form of mediation will be used to reduce the chances of making a type 1 error[49]. This will allow for exploration of whether cognitive fusion mediates the relationship between maladaptive schema modes and eating disorder severity.

Methods

Participants were recruited from three specialist eating disorder services within Scotland. One was an inpatient service whilst the other two were outpatient services. Potential participants needed to have met the following inclusion criteria:

- Participants had a diagnosis of Anorexia Nervosa, Atypical Anorexia Nervosa, Bulimia Nervosa or Atypical Bulimia Nervosa according to ICD−10 diagnostic criteria. This was assessed by a trained clinician working within the various specialist eating disorder services.
- Participants were between the ages of 18 and 65 years.

- Participants already engaged in treatment had not had more than five ACT or schema therapy sessions.
- Participants had good command over the English Language to complete the questionnaires.

Measures

All participants were asked to complete the following three questionnaires;

- *The Schema Mode Inventory (SMI, 1.1)*[35]
- *Eating Disorders Examination Questionnaire (EDEQ)*[36]
- *Cognitive Fusion Questionnaire (CFQ-13)*[37]

Procedure

Individuals were identified through their attendance at one of the aforementioned eating disorder services. Inclusion criteria was established by a trained clinician and all individuals who met the inclusion criteria were invited to take part Questionnaire completion took approximately 45 minutes on one single occasion. Due to eating disorder symptoms possibly fluctuating over time, it was ensured that all questionnaires were completed together.

Ethical review

The study was reviewed and approved by the Clinical Psychology Ethics Committee at the University of Edinburgh; the North of Scotland Research Ethics Committee and NHS Multisite Research and Development team.

Design/Statistics

Within subjects Pearson's correlations were used. The independent variable was eating disorder severity (taken from the EDE-Q) and the dependent variables were participants scores on the CFQ-13 and SMI-1.1.

Data was then screened to ensure basic assumptions of regression analysis were met. This included checks of multicollinearity, the use of Durbin-Watson to check whether the residuals in the model were independent and inspection of histograms to ensure normal distribution. As no assumptions were violated Stepwise regression was then conducted to explore which of the schema modes were most predictive of eating disorder severity.

Finally, Bootstrapping was used to determine if the severity of maladaptive schema modes predicted eating disorder severity independent of cognitive fusion or whether the process of cognitive fusion mediated this relationship to some extent.

Participants

In total 121 questionnaire packs were given out and 50 invitation letters were posted by clinicians to potential participants. A further proportion of individuals were asked in person if they would like to participate and declined. In total the response rate was 33 (19%). Two participants were excluded from analysis. One was found to have a learning disability and was unable to complete the majority of the questionnaires. The other did not fully complete the consent form. The proportion of participants from outpatient services was 23 (71%) and from inpatient services 10 (29%). Finally, 100% of the participants were female.

Results

Distribution of data

In order to determine if the data was normally distributed kolmogorov-smirnov tests of normality were applied. The distributions of the EDE-Q ($D(31)= 0.13$, $p=.20$), CFQ-13 ($D(31)= 0.15$, $p=.09$) and SMI-1.1 ($D(31)= 0.12$, $p=.20$) were not significantly different from normal. This shows the data does not violate the assumptions of normality therefore parametric tests were used.

Descriptive statistics

The average questionnaire scores can be seen in table 1.

Table 1. Maximums, minimums, means and standard deviations on the SMI-1.1, CFQ-13 and the EDE-Q (plus weight concern, shape concern, eating concern and restraint subscales). *n=31*.

	Max score	**Min score**	**Mean**	**Standard deviation**
EDE-Q Mean score	5.75	0.54	3.95	1.34
EDE-Q Weight concern	6.00	0.60	4.17	1.46
EDE-Q Shape concern	6.00	1.36	4.67	1.45
EDE-Q Eating concern	6.00	0.00	3.53	1.48
EDE-Q Restraint	6.00	0.00	3.40	1.73
Maladaptive SMI-1.1 score	3.79	1.30	2.91	0.57
CFQ-13 score	81	20	61	12.26

Aim 1. Is there a relationship between schema modes and eating disorder severity?

Visual analysis of the data in figure 1 suggests a positive linear relationship between schema modes and eating disorder severity. In order to further explore this Pearson's *r* correlation analysis were conducted between each participant's mean maladaptive schema mode score on the SMI-1.1 (the two adaptive modes, the *Happy Child* and *Healthy Adult*, were removed prior to this analysis) and the mean global eating disorder severity score on the EDE-Q.

This demonstrated a positive correlation between these two measures (r=.751, p<. 001) which accounted for 56% of the variance. These results suggest the more severe the eating disorder symptoms the more severe participants' maladaptive schema modes were and vice-versa.

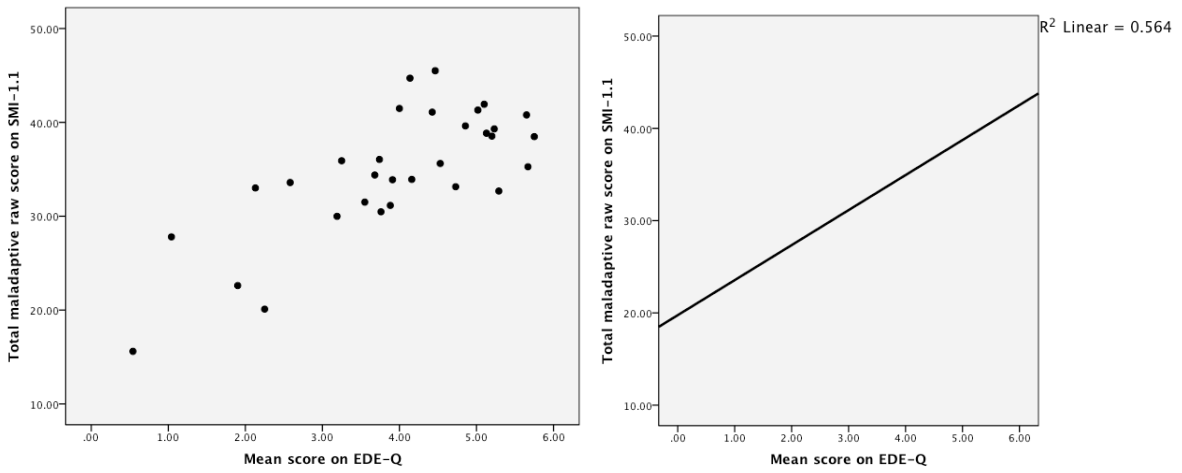

Figure 1. Graph and regression line to show the relationship between participants' scores on the EDE-Q and the SMI-1.1 (*n*=31).

In order to determine if particular schema modes were more associated with eating disorder severity, additional correlation analyses were conducted. These revealed significant correlations between eating disorder severity (EDE-Q global score) and the *Vulnerable Child* mode (*r*=.607, *p*<.001); *Angry Child* mode (*r*=.503, *p*=.004); *Undisciplined Child* mode (*r*=.609, *p*<.001); *Compliant Surrenderer* mode (*r*=.530, *p*=.002); *Detached Self-soother* mode *(r*=.713, *p*<.001); *Self Aggrandise*r mode (*r*=. 460, *p*=.009); *Punitive Parent mode* (*r*=.524, *p*=.002) and the *Demanding Parent* (*r*=. 610, *p*<.001).

In contrast the following modes were **not** significantly associated with eating disorder severity; the *Enraged Child* (*r*=.322, *p*=.078), *Impulsive Child* (*r*=.246, *p*=.182), *Happy Child* (*r*=-.176, *p*=.345), *Detached Protector* (*r*=.246, *p*=.183), *Bully and Attack* (*r*=.043, *p*=.820) and the *Healthy Adult* mode (*r*=-.198, *p*=.284). These results demonstrate some specificity in the relationship between eating disorder severity and schema modes.

In order to determine which of the schema modes were most predictive of eating disorder severity stepwise regression was conducted. Overall this model demonstrated that the *Detached Self-Soother* ($t(30)= 4.27$, standardised $b=.55$, $p<.001$) and the *Vulnerable Child* ($t(30)= 2.83$, standardised $b= .37$, $p=.009$) modes were the most predictive of eating disorder severity. This relationship is positive suggesting that the more severe the *Detached Self-Soother* and *Vulnerable Child* the more severe the eating disorder.

Aim 2. Is there a relationship between cognitive fusion and eating disorder severity?

As can be seen in figure 2, visual analysis suggests a positive linear relationship between cognitive fusion and eating disorder severity. In order to further explore this Pearson's *r* correlation analysis was conducted between each participant's mean global score on the EDE-Q and the CFQ-13. This demonstrated a positive correlation between these two measures ($r=.706$, $p<.001$), which accounted for 50% of the variance. These results suggest that the more severe the eating disorder symptoms the higher the participants' scores were on the CFQ-13. These results demonstrate that as fusion and entanglement with thinking increases, so does eating pathology and vice versa.

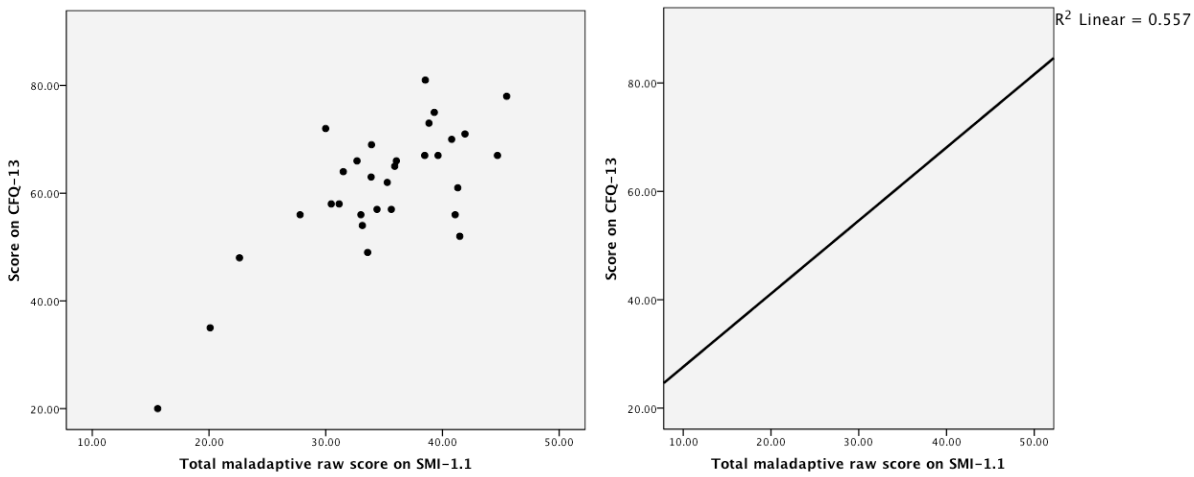

Figure 2. Graph and regression line to show the relationship between participants' scores on the EDE-Q and the CFQ-13 (*n*=31).

Is there a relationship between participants' scores on the SMI-1.1 and the CFQ-13?

In order to further explore this Pearson's *r* correlation analysis was conducted between each participant's raw maladaptive schema mode score on the SMI-1.1 and the CFQ-13. This demonstrated a positive correlation between these two measures (r=.747, p<.001), which accounted for 56% of the variance. These results demonstrate that as fusion and entanglement with thinking increases, so does the severity of participants' maladaptive schema modes and vice versa.

In order to determine whether schema modes predicted eating disorder severity independent of cognitive fusion or whether the process of cognitive fusion mediated this relationship, Bootstrapping was used. Results of the indirect effect, based on a bootstrapped sample of n = 5,000, revealed that zero was contained within the lower and upper limits (*BC* lower = -49.47, *BC* upper = 0.88), thus indicating that cognitive fusion did not mediate the relationship between schema modes and eating disorder severity when using this method.

Discussion

A positive relationship was found between maladaptive schema modes and eating disorder severity. This means that the more severe participants' maladaptive schemas were the more severe the eating disorder symptoms and vice versa. Further exploration of this relationship identified a number of schema modes that were significantly associated with eating disorder symptom severity. These included the *Vulnerable Child*, *Angry Child*, *Undisciplined Child*, *Compliant Surrenderer*, *Detached Self-soother*, *Self Aggrandiser*, *Punitive Parent* and the *Demanding Parent*. All of these

relationships were positive, indicating that the more severe the schema mode the more severe the eating disorder.

The following modes were **not** significantly related to eating disorder severity; the *Enraged Child, Impulsive Child, Happy Child, Detached Protector, Bully and Attack* and the *Healthy Adult* modes. The overall prevalence and severity of schema modes found in this sample of participants suggests that schema mode therapy may be suited to individuals with complex eating disorders. Finally, stepwise regression demonstrated that the two modes most predictive of eating disorder severity were the *Detached Self-Soother* and the *Vulnerable Child*. This relationship was positive suggesting higher scores on these modes was predictive of more severe eating disorders.

Although this finding is consistent with the correlation results, the small sample size in this study mean caution should before generalising these results.Although all the maladaptive schema modes can have a detrimental effect on an individual's life and functioning, the *Vulnerable Child* mode is seen as one of the most important for mode work[17]. The above findings also demonstrate that it may be one of the most important for working therapeutically with individuals who have an eating disorder. When activated, this mode triggers strong emotions such as dysphoric or anxious affect, especially fear and sadness[17]. Likewise, the *Angry Child* and the *Undisciplined Child* may also trigger strong emotional responses. The *Angry Child* is associated with feelings of anger and frustration typically due to the needs of the *Vulnerable Child* not been met. The *Undisciplined Child* mode will make it hard for the individual to delay gratification of needs and, although speculative, it may be hypothesised that this particular mode could be associated with a tendency to binge

and purge. Importantly, the presence of these child modes indicates that this group of participants may have a large number of unmet needs that result in them experiencing strong negative affect.

As previously discussed, there is a recognition that one potential function of an eating disorder may be to avoid overwhelming negative emotional experiences[40,41]. In this way it is possible that individuals may use eating disordered behaviours to regulate (or cope with) unbearable emotions which may be originating from the activation of schema modes (in particular, the child modes). When the distress becomes too great for the individual, it may be hypothesised that they flip onto a coping mode to distract, reduce or detach from these painful emotions.

Of the coping modes, the *Detached Self-Soother* was found to be the most significant in this sample. This is an active avoidant coping mode as individuals attempt to engage in activities that will soothe or distract them from feeling. Eating pathology such as binging, purging etc. may be examples of such activities. Unfortunately this mode may block the use of more adaptive coping mechanisms such as using interpersonal support to meet underlying needs. By failing to address these underlying factors, there will continue to be a need for coping strategies and eating disordered behaviours.

The *Compliant Surrenderer* mode is also an avoidant coping mode that was significant in this sample. When triggered, individuals avoid focusing on their own needs and emotions by focusing on the needs and feelings of others. Individuals with severe levels of this mode are unlikely to ask other people to meet their personal needs and may also allow others to make decisions on their behalf. This

mode is hypothesised to also compensate for underlying fears of defectiveness or being rejected. Thus individuals may seek to gratify the needs of others through fear of personal rejection. Although this mode is a short term coping strategy intended to reduce negative affect, overtime it may be speculated that it could result in a degree of anger and frustration due to personal needs remaining unfulfilled. As previously discussed, the *Angry Child* is often triggered when the needs of the *Vulnerable Child* are unmet. In this way, the *Compliant Surrenderer* mode may inadvertently trigger the child modes.

It is interesting that the *Detached Protector* mode is not significantly associated with eating pathology. Although speculative, if the *Detached Protector* is indeed not associated with eating pathology, then it is possible that the individual may feel more reliant on the *Detached Self-Soother* and *Compliant Surrenderer* modes to avoid intolerable emotional experiences. Unfortunately, the *Detached Self-Soother* in particular may increase the use and need of different forms of eating pathology.

Although not associated with eating severity, the mean score on the *Detached Protector* is still high when compared to the norms developed in Lobbestael *et al's*[42] study. This finding suggests that the relationship between the *Detached Protector* and eating pathology is not about severity. Considered in light of Waller's[22] hypothesis, this may be due to the *Detached Protector* being a primary affect avoidance strategy whilst the *Detached Self-Soother* is potentially a secondary affect avoidance strategy. According to Waller[22], the main difference between primary and secondary avoidance is the point at which individuals try to cope with unbearable emotions. Primary affect avoidance aims to avoid emotional activation altogether whereas secondary strategies attempt to manage emotions already triggered.

Based on these differences, it could be anticipated that individuals with severe restrictive eating disorders (pure AN) would have higher levels of the *Detached Protector.* This would be due to restriction often resulting in complete detachment from emotions which therefore requires no secondary (or compensatory) strategies to be employed. In contrast, individuals who use active compensatory strategies (which would include Atypical Anorexia Nervosa, Bulimia Nervosa and Atypical Bulimia Nervosa) might have higher levels of the *Detached Self-Soother*.

In order to test this hypothesis the data would needed to have been split into two groups; a restrictive group and a compensatory group. Unfortunately, this study did not have enough power to conduct this form of analysis. However, it was possible to look at schema modes associated with the different EDE-Q subscales. Of the different sub-scales the restriction subscale was considered to most closely measure pure anorexic pathology. Interestingly, no relationship was found between the *Detached Protector* and the restriction subscale. However, as the EDE-Q does not have a specific bulimic subscale and pure anorexia is more complicated than purely measuring restriction, it is difficult to draw any conclusions in regard to eating disorder diagnosis and schema modes from this data. Finally, it should be noted that Waller's model was based on schemas rather than schema modes therefore the modes can only be speculated. Additionally, Waller[22] referred to differences between restrictive (compulsive) coping strategies and bulimic (impulsive) coping strategies. Based on this hypothesis, it might have been anticipated that the *Impulsive Child* mode would have been prevalent within this population. The absence of this mode is at odds with Waller's[22] schema based model.

The final coping mode found in this group of participants was the *Self-Aggrandizer*. This mode is an overcompensatory mode which is characteristic of a narcissistic personality style and manifests via self absorption and also a lack of empathy for others[43]. These behaviours are hypothesised to develop early in life to compensate for or gratify core unmet needs[17]. Within an eating disorder population it is possible that the strength of this mode reflects the individual's strong attachment to their eating disorder and absorption in maintaining control over eating behaviour. For some, it may reflect a sense of pride in their achievement and body image. Again, this coping mode may function in the short term to manage unbearable emotional experiences. However, without alternative (adaptive) coping strategies aimed at gratifying unmet needs, the presence of this mode could potentially increase the presence and severity of eating disorder symptoms.

Finally, both parent modes were characteristic of this sample of participants. The parent modes represent the internalised experience of overly critical or demanding parents. When activated the *Punitive Parent* mode results in the individual feeling that they (or others) deserve punishment or blame. This often results in individuals acting in a blaming, punishing, or abusive way towards themselves or others. The *Demanding Parent* mode results in the individual feeling that there is a "right" way to be. For example, they may feel that they need to be perfect or achieve at a very high level or that it is wrong to express feelings.

Although speculative, it might be hypothesised that these modes become triggered by eating behaviour, possibly critiquing the individual and demanding they maintain control over eating. This might be more likely if there had been rules around food during childhood, or if they had become aware of their parents' own values and

judgements about body size. Although parental values and judgements may have been directed toward themselves (rather than the child), children may selectively identify with the parents' value system. The Demanding Parent mode in particular can develop through selective identification (Young *et al.,* 2003). In very restrictive eating disorders the parent modes may be activated at the sight of food, perhaps criticising the individual's hunger or desire while the *Demanding Parent* mode encourages them to stay on track with their diet and avoid eating and/or food.

In primarily bulimic pathologies the child modes may become overwhelmed by the criticisms originating from the parent modes. This may result in the individual switching into the *Detached-Self Soother* mode to escape the shame and anxiety generated by the child modes. The *Detached-Self-Soother* may then allow them to eat (or binge). However, after the individual has eaten, the parent modes are likely to return again, triggering intense feelings of guilt and disgust. The parent modes may then chastise and shame the individual into compensatory measures such as vomiting, laxative misuse or over-exercise.

Although research into schema *modes* is still very much in its infancy, previous research has found relationships between eating disorders symptoms and singular schemas[19,20,21,44]. Therefore, this research builds on the current evidence by demonstrating that schema modes, the most recent development in schema therapy, are also associated with eating disorders symptoms. Furthermore, it suggests that particular modes may be characteristic in an eating disorder population.

Overall, these findings suggest that due to the prevalence and severity of schema modes found in this group of participants and the relationship between maladaptive

schema modes and eating pathology, that schema mode therapy may be beneficial for individuals who have an eating disorder. This builds on the work of Simpson *et al.*[24] who demonstrated the clinical effectiveness of group schema therapy in an outpatient eating disorder service.

Building on the positive outcomes displayed by Simpson *et al.*[24], future research could pilot the mode model within an eating disorder service to test this hypothesis. Additionally, it would also be interesting to see what happens to schema modes if you successfully treat eating disorder symptoms and behaviours. It might be hypothesised that schema modes become less severe. However, to test this longitudinal research, monitoring the severity of schema modes over the course of treatment is needed.

A positive relationship was also found between the process of cognitive fusion and the severity of eating disorder symptoms. This means that the greater the level of cognitive fusion the more severe the eating disorder symptoms. Cognitive fusion has been described as the process by which thoughts about an event become fused with the actual event[45] and also as the 'excessive attachment to the literal content of thought that makes healthy psychological flexibility difficult or impossible'[46]. Therefore individuals with high cognitive fusion are more likely to fuse themselves and their identity with their language system and experience.

This process has the potential to either initiate or maintain eating pathology. For example, most individuals at some time are likely to have unhelpful thoughts about food or themselves. These may be in response to a negative experience of eating (such as getting food poisoning or overindulgence) or in response to a negative

consequence (such as gaining undesired weight). However, despite having negative experiences or consequences most people are able to identify thoughts as just that, thoughts. An individual with higher levels of cognitive fusion is less likely to be able to think flexibly about such thoughts and more likely to view them literally. Although this process is not harmful in itself, it often results in behavioural change and avoidance which can be. For example, if an individual has a negative thought about food which results in them restricting food intake, then there is a potential to develop eating pathology (or maintain existing pathology).

Although this is the first study to explore the link between eating disorders and the process of cognitive fusion other studies have looked at other ACT concepts in the field of eating disorders. For example, dietary restraint had been associated with non-acceptance of emotion and experiential avoidance[31] and conversely, acceptance and greater psychological flexibility has been associated with healthier eating habits and lower levels of weight related shame[30]. Finally, the more recent work of Sandoz[32] has demonstrated that rigid inflexible beliefs were associated with body dissatisfaction and disordered eating[32]. This study would support and build on such findings demonstrating that the process of cognitive fusion (an integral part of psychological flexibility) is also associated with eating pathology.

Can we make any predictions based on these results?

Overall, it appears that cognitive fusion did not mediate the relationship between schema modes and eating disorder severity. However due to the relatively small sample size in this study it is possible that this research did not have enough power to detect such an effect if it were to exisit. It is therefore recommended that future

research might further examine this relationship within a larger sample of participants.

Interestingly, stepwise regression indicated that two modes in particular appear to best predict eating disorder severity. These are the Detached Self-soother and the Vulnerable Child modes. However as previously mentioned, to conduct this form of regression it is recommended that a minimum of ten participants per predictor variable are recruited to ensure the sample has enough power to detect relationships. Excluding the two healthy modes, there are 12 predictors which would require a minimum of 120 participants. This study only had 31 so was likely to be underpowered.

Clinical implications

Overall these findings demonstrate that both maladaptive schema modes and the process of cognitive fusion are associated with eating disorders. In turn, this suggests that therapeutic interventions designed to reduce the severity of maladaptive schema modes and cognitive fusion may reduce eating disorder symptoms. As no controlled research has yet tested the schema mode model in an eating disorder population, this can only be speculated based on the positive outcomes of an uncontrolled case series design into group schema therapy by Simpson *et al*[24]. In relation to ACT, cognitive fusion and psychological flexibility are key components in the model. As such clinicians using ACT will naturally account for effects of cognitive fusion within therapy. The recent study by Juarascio *et al*[10] empirically tested this model in a group of individuals with an eating disorder. These findings suggested that ACT is effective in reducing eating disorder symptoms.

However, only 4% of participants in this study had a formal diagnosis of an eating disorder. The majority of participants had subclinical eating disorders. Therefore the efficacy of ACT in more complex, severe eating disorders has yet to be established.

These results also have implications for the assessment and clinical formulation of complex eating disorders. Both the schema mode inventory and the cognitive fusion questionnaire provide valuable information that could complement the assessment process. For example, in schema mode therapy, by identifying and understanding the interplay between child modes, coping modes and parent modes, links may be formed to understand the possible function of the eating disorder. It might be that an individual is found to have a large number of severe maladaptive child modes that when triggered induce strong 'unbearable' emotions. They may also have severe maladaptive coping modes that function to block out or manage these unbearable emotions. If such modes were present, the therapist would have two primary goals; firstly to meet the underlying needs of the child modes and reduce the intensity and frequency of the related negative affect. This should also reduce the need for the maladaptive coping modes. Secondly, to look at alternative ways to manage or respond to emotional experiences. It is beyond the scope of this paper to go into detailed schema mode treatment strategies. Therapists looking for such information should refer to the treatment manual written by Young *et al*[17].

In regard to cognitive fusion, should an individual be found to have high levels of cognitive fusion, there may be implications for the timing of cognitive work. For example, someone with very severe eating pathology is likely to demonstrate more rigid, inflexible thinking patterns. This would make cognitive techniques (such as

thought challenging) more difficult. If such techniques are to be used, waiting until later in treatment, when cognitive rigidity declines, may be more helpful and effective. This is at odds with current guidelines which promote CBT for all eating disorders. Rather than seeing eating disorders as a heterogeneous group, treatment needs to be planned based on a strong formulation that takes into account the function of eating disorder symptoms. Assessment of schema modes and level of cognitive fusion may provide information to help with this process.

Taken together, these findings suggest that both models may warrant further testing and exploration within eating disorder services. However, both these therapies require knowledge and training before being attempted. Schema therapy in particular also requires supervision and team support. Therefore, clinical departments interested in exploring these treatments should first seek training and advice.

Strengths and Limitations

This study provides the first exploration of the relationship between schema modes, cognitive fusion and eating disorder symptoms. It benefits from being highly naturalistic in that all individuals attending the services were considered. No individuals were screened or excluded for co-morbid difficulties (such as anxiety, depression, substance misuse or personality disorder). The sample were therefore considered representative of individuals attending specialist services. This makes the results more generalisable to other similar services. However, failure to screen for co-morbid anxiety, depression and personality disorders leaves open the possibility that such factors may be influencing the relationship found between maladaptive schema modes, cognitive fusion and eating disorder severity.

In particular previous research has shown that specific schema modes profiles appear characteristic of individual personality disorder diagnosis[42.] For example, Borderline Personality Disorder is characterised by the *Vulnerable Child, Angry Child, Impulsive Child, Undisciplined Child, Detached Protector* and *Punitive Parent* modes whilst Narcissistic Personality Disorder is characterised by the *Self-Aggrandiser, Detached Self-Soother, Enraged Child* and *Vulnerable Child* modes[42]. Excluding the *Detached Protector* and the *Enraged Child* modes, all these modes were characteristic of this sample. This limitation leaves open the possibility that co-morbid personality disorders may be accounting for some of the relationship between schema modes and eating disorder severity. Future research could expand on this research by screen for co-morbid personality disorders, anxiety and depression.

Another benefit of this study was that it recruited individuals at various stages in treatment. This was to allow representation of individuals at different stages in treatment with different levels of need. This design allowed a greater range and distribution of scores. Some participants were nearly recovered whilst others were acutely unwell. As participants completed all the questionnaires together, any changes in eating disorder severity was reflected on the EDE-Q. This makes these findings generalisable to individuals at different stages in treatment. A potential limitation of this recruitment strategy is that it is only generalisable to other specialist services. Future research could build on this study by looking at a greater range of eating disorder services, including subclinical populations and individuals seen within primary care settings.

One of the biggest weaknesses of this research is its failure to unravel causality. Although the construct of schema modes and process of cognitive fusion appear to be related to eating disorder severity what cannot be determined from the current results is the nature of this relationship. For example, does the presence of specific schema modes/cognitive fusion predispose individuals to develop an eating disorder? Longitudinal research tracking schemas and cognitive fusion over the course of an eating disorder would be needed to establish whether or not this is the case. Despite this flaw, the empirical support for both ACT and schema therapy in treating eating disorder symptoms suggests that the nature of this relationship may not affect therapeutic outcomes[24,10].

Finally, this study has a relatively small sample size. This limitation may have resulted in the mediation analysis and the stepwise regression being under powered to detect existing effects. In order to improve on this study future research should attempt to

recruit a much larger sample of participants to increase the generalisability of these findings.

Future Research

Building on the results of this study there are various directions for future research. The clinical evidence base for both schema mode therapy and acceptance and commitment therapy in the field of eating disorders is still in its infancy. Based on the findings of this study and the positive outcomes of Simpson *et al.,* 2010 and Juarascio *et al.,* 2010 these therapies warrant further exploration in the field of eating disorders. Developments could either focus on reducing the impact of maladaptive schema modes or on changing the stance individuals take towards their thoughts and private mental events. Ultimately, these avenues may lead to improvements in our understanding of eating pathology and better therapeutic outcomes.

In the current economic climate, clinical departments are constantly trying to provide the best psychological interventions in the most cost effective way. So far only group schema therapy has been tested within an eating disorder population (Simpson *et al.,* 2010). Therefore, future research could be the first to pilot individual schema therapy sessions in an eating disorder service to determine which format is most effective.

Additionally, as yet no longitudinal research has tracked the impact of maladaptive schema modes or cognitive fusion over the course of an eating disorder. Therefore, it would also be interesting to identify whether particular schema modes and cognitive fusion are present before the onset of eating pathology and whether these

become more severe as the eating disorder progresses. Such research may help to unravel causality by identifying whether the presence of maladaptive modes and/or cognitive fusion predispose an individual to develop eating pathology.

In regard to cognitive work, future research could explore the effectiveness of cognitive strategies (such as thought challenging) at different stages of treatment. The CFQ-13 could be used throughout treatment alongside measures of eating disorder severity to identify the point at which cognitive fusion and eating pathology decline. It would be particularly interesting to see which improves first. Such research may help to determine whether cognitive fusion predisposes eating pathology or whether it is a symptom of eating pathology.

Finally, future research could further develop and test the most recent mode model developed for individuals with an eating disorder (Simpson, in press). This may involve generating a modified mode questionnaire containing items to assess the presence of the new modes such as the *Perfectionistic Controller, Needy Child* and the *Shame/Deprived Child* mode. Analysis could then be conducted to determine whether the adapted schema modes encapsulate complex eating disorders better than the original mode model.

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Appendix Contents

Appendix A

Date:

SMI (Version 1.1)

INSTRUCTION: Listed below are statements that people might use to describe themselves. Please rate each item based on **how often** you believe or feel each statement **in general** using the frequency scale.

FREQUENCY: In general	
1= Never or Almost Never	4= Frequently
2= Rarely	5= Most of the time
3= Occasionally	6= All of the time

Frequency	**In general...**
	1. I demand respect by not letting other people push me around.
	2. I feel loved and accepted.
	3. I deny myself pleasure because I don't deserve it.
	4. I feel fundamentally inadequate, flawed, or defective.
	5. I have impulses to punish myself by hurting myself (e.g., cutting myself).
	6. I feel lost.
	7. I'm hard on myself.
	8. I try very hard to please other people in order to avoid conflict, confrontation, or rejection.
	9. I can't forgive myself.
	10. I do things to make myself the center of attention.
	11. I get irritated when people don't do what I ask them to do.
	12. I have trouble controlling my impulses.
	13. If I can't reach a goal, I become easily frustrated and give up.
	14. I have rage outbursts.
	15. I act impulsively or express emotions that get me into trouble or hurt other people.
	16. It's my fault when something bad happens.
	17. I feel content and at ease.
	18. I change myself depending on the people I'm with, so they'll like me or approve of me.
	19. I feel connected to other people.
	20. When there are problems, I try hard to solve them myself.
	21. I don't discipline myself to complete routine or boring tasks.
	22. If I don't fight, I will be abused or ignored.
	23. I have to take care of the people around me.
	24. If you let other people mock or bully you, you're a loser.
	25. I physically attack people when I'm angry at them.
	26. Once I start to feel angry, I often don't control it and lose my temper.

	27. It’s important for me to be Number One (e.g., the most popular, most successful, most wealthy, most powerful).
	28. I feel indifferent about most things.
	29. I can solve problems rationally without letting my emotions overwhelm me.
	30. It’s ridiculous to plan how you’ll handle situations.
	31. I won’t settle for second best.
	32. Attacking is the best defense.
	33. I feel cold and heartless toward other people.
	34. I feel detached (no contact with myself, my emotions or other people).
	35. I blindly follow my emotions.
	36. I feel desperate.
	37. I allow other people to criticize me or put me down.
	38. In relationships, I let the other person have the upper hand.
	39. I feel distant from other people.
	40. I don't think about what I say, and it gets me into trouble or hurts other people.
	41. I work or play sports intensively so that I don’t have to think about upsetting things.
	42. I’m angry that people are trying to take away my freedom or independence.
	43. I feel nothing.
	44. I do what I want to do, regardless of other people’s needs and feelings.
	45. I don’t let myself relax or have fun until I’ve finished everything I’m supposed to do.
	46. I throw things around when I’m angry.
	47. I feel enraged toward other people.
	48. I feel that I fit in with other people.
	49. I have a lot of anger built up inside of me that I need to let out.
	50. I feel lonely.
	51. I try to do my best at everything.
	52. I like doing something exciting or soothing to avoid my feelings (e.g., working, gambling, eating, shopping, sexual activities, watching TV).
	53. Equality doesn’t exist, so it’s better to be superior to other people.
	54. When I’m angry, I often lose control and threaten other people.
	55. I let other people get their own way instead of expressing my own needs.
	56. If someone is not with me, he or she is against me.
	57. In order to be bothered less by my annoying thoughts or feelings, I make sure that I’m always busy.
	58. I’m a bad person if I get angry at other people.
	59. I don’t want to get involved with people.
	60. I have been so angry that I have hurt someone or killed someone.
	61. I feel that I have plenty of stability and security in my life.
	62. I know when to express my emotions and when not to.
	63. I’m angry with someone for leaving me alone or abandoning me.

	64. I don’t feel connected to other people.
	65. I can’t bring myself to do things that I find unpleasant, even if I know it’s for my own good.
	66. I break rules and regret it later.
	67. I feel humiliated.
	68. I trust most other people.
	69. I act first and think later.
	70. I get bored easily and lose interest in things.
	71. Even if there are people around me, I feel lonely.
	72. I don’t allow myself to do pleasurable things that other people do because I’m bad.
	73. I assert what I need without going overboard.
	74. I feel special and better than most other people.
	75. I don’t care about anything; nothing matters to me.
	76. It makes me angry when someone tells me how I should feel or behave.
	77. If you don’t dominate other people, they will dominate you.
	78. I say what I feel, or do things impulsively, without thinking of the consequences.
	79. I feel like telling people off for the way they have treated me.
	80. I’m capable of taking care of myself.
	81. I’m quite critical of other people.
	82. I’m under constant pressure to achieve and get things done.
	83. I’m trying not to make mistakes; otherwise, I’ll get down on myself.
	84. I deserve to be punished.
	85. I can learn, grow, and change.
	86. I want to distract myself from upsetting thoughts and feelings.
	87. I’m angry at myself.
	88. I feel flat.
	89. I have to be the best in whatever I do.
	90. I sacrifice pleasure, health, or happiness to meet my own standards.
	91. I’m demanding of other people.
	92. If I get angry, I can get so out of control that I injure other people.
	93. I am invulnerable.
	94. I’m a bad person.
	95. I feel safe.
	96. I feel listened to, understood, and validated.
	97. It is impossible for me to control my impulses.
	98. I destroy things when I’m angry.
	99. By dominating other people, nothing can happen to you.
	100. I act in a passive way, even when I don’t like the way things are.
	101. My anger gets out of control.
	102. I mock or bully other people.

	103. I feel like lashing out or hurting someone for what he/she did to me.
	104. I know that there is a 'right' and a 'wrong' way to do things; I try hard to do things the right way, or else I start criticizing myself.
	105. I often feel alone in the world.
	106. I feel weak and helpless.
	107. I'm lazy.
	108. I can put up with anything from people who are important to me.
	109. I've been cheated or treated unfairly.
	110. If I feel the urge to do something, I just do it.
	111. I feel left out or excluded.
	112. I belittle others.
	113. I feel optimistic.
	114. I feel I shouldn't have to follow the same rules that other people do.
	115. My life right now revolves around getting things done and doing them 'right'.
	116. I'm pushing myself to be more responsible than most other people.
	117. I can stand up for myself when I feel unfairly criticized, abused, or taken advantage of.
	118. I don't deserve sympathy when something bad happens to me.
	119. I feel that nobody loves me.
	120. I feel that I'm basically a good person.
	121. When necessary, I complete boring and routine tasks in order to accomplish things I value.
	122. I feel spontaneous and playful.
	123. I can become so angry that I feel capable of killing someone.
	124. I have a good sense of who I am and what I need to make myself happy.

Appendix B

EATING DISORDER – EDE-Q

Name: Date:

Instructions: The following questions are concerned with the past four weeks (28 days) only.
Please read each item carefully. Please answer all of the questions. Thank you.
Questions 1 to 12: Please circle the appropriate number on the right. Remember that the questions only refer to the past four weeks (28 days) only.

On how many of the past 28 days….	No Days	1-5 Days	6-12 Days	13-15 Days	16-22 Days	23-27 Days	Every Day
1. Have you been deliberately trying to limit the amount of food you eat to influence your shape and weight (whether or not you have succeeded?)	0	1	2	3	4	5	6
2.Have you gone for long periods of time (8 waking hours or more) without eating anything at all in order to influence your shape and weight?	0	1	2	3	4	5	6
3. Have you tried to exclude from your diet any foods that you like in order to influence your shape or weight (Whether or not you have succeeded)?	0	1	2	3	4	5	6
4. Have you tried to follow definite rules regarding your eating (for example, a calorie limit) in order to influence your shape or weight (whether or not you have succeeded)?	0	1	2	3	4	5	6
5. Have you had a definite desire to have an empty stomach with the aim of influencing your shape or weight?	0	1	2	3	4	5	6
6. Have you had a definite desire to have a totally flat stomach?	0	1	2	3	4	5	6

7. Has thinking about food, eating or calories made it very difficult to concentrate on things you are interested in (For example, working, following a conversation, or reading)?	0	1	2	3	4	5	6
8. Has thinking about shape or weight made it very difficult to concentrate on things you are interested in (For example, working, following a conversation, or reading)?	0	1	2	3	4	5	6
9. Have you had a definite fear of losing control over eating?	0	1	2	3	4	5	6
10. Have you had a definite fear that you might gain weight?	0	1	2	3	4	5	6
11. Have you felt fat?	0	1	2	3	4	5	6
12. Have you had a strong desire to lose weight?	0	1	2	3	4	5	6

Questions 13-18: Please fill in the appropriate number in the boxes on the right. Remember that the questions only refer to the past four weeks (28 days).

13. Over the past 28 days, how many times have you eaten what other people would regard as an unusually large amount of food (given the circumstance) ?

……..

14. On how many of these times did you have a sense of having lost control over your eating (at the time that you were eating)?

……

15. Over the past 28 days, on how many DAYS have such episodes of overeating occurred (i.e., you have eaten an unusually large amount of food and had a sense of loss of control at the time)?.

……

16. Over the past 28 days, how many times have you made yourself sick (vomit) as a means of controlling your shape or
weight? ……..

17. Over the past 28 days, how many times have you taken laxatives as a means of controlling your shape or weight?

……

18. Over the past 28 days, how many times have you exerciserd in a “driven” or “compulsive” way as a means of controlling your weight, shape or amount of fat, or to burn off calories?

……

Questions 19-21: Please circle the appropriate number. Please note that for these questions the term “binge-eating” means eating what others would regard as an unusually large amount of food for the circumstances, accompanied by a sensse of having lost control over eating.

	No Days	1-5 Days	6-12 Days	13-15 Days	16-22 Days	22-27 Days	Every day
19.Over the past 28 days, on how many days have you eaten in secret (ie, furtively) …….Do not count episodes of binge eating	0	1	2	3	4	5	6
	None of the times	A few times	Less than half	Half of the times	More than half	Most of the times	Every time
20. On what proportion of the times that you have eaten have you felt guilty (felt that you have done wrong) because of its effect on your shape or weight? …….Do not count episodes of binge eating.	0	1	2	3	4	5	6
	Not at all	Sligh	tly	Modera	tely	Mark	edly
21. Over the past 28 days, how concerned have you been about other people seeing what you eat? …..Do not count episodes of binge eating.	0	1	2	3	4	5	6

Questions 22 to 28: Please circle the appropriate number on the right. Remember that the questions only refer to the past four weeks (28 days).

	Not at all	Sligh	tly	Modera	tely	Mark	edly
22.Has your weight influenced how you think about (judge) yourself as a person.	0	1	2	3	4	5	6

23. Has your shape influenced how think about (judge) yourself as a person.	0	1	2	3	4	5	6
24 . How much would it have upset you if you had been asked to weigh yourself once a week (no more, or less often) for the next four weeks?	0	1	2	3	4	5	6
25. How dissatisfied have you been with your weight?	0	1	2	3	4	5	6
26. How dissatisfied have you been with your shape?	0	1	2	3	4	5	6
27. How uncomfortable have you felt seeing your body (for example, seeing your shape in the mirror, in a shop window reflection, while undressing or taking a bath or a shower)?	0	1	2	3	4	5	6
28. How uncomfortable have you felt about others seeing your shape or figure (For example, in communal changing rooms, when swimming, or wearing tight clothes)?	0	1	2	3	4	5	6

What is your weight at present (Please give your best estimate) ……..

What is your height? ……

If female: Over the past three-to-four months have you missed your menstrual periods?

……..

If so, how many? ……..

Have you been taking the “pill” ……..

THANK YOU

Appendix C

CFQ13

Below you will find a list of statements. Please rate how true each statement is for you by circling a number next to it. Use the scale below to make your choice.

1	2	3	4	5	6	7
never true	**very seldom true**	**seldom true**	**sometimes true**	**frequently true**	**almost always true**	**always true**

1.	My thoughts cause me distress or emotional pain	1	2	3	4	5	6	7
2.	I get so caught up in my thoughts that I am unable to do the things that I most want to do	1	2	3	4	5	6	7
3.	Even when I am having distressing thoughts, I know that they may become less important eventually	1	2	3	4	5	6	7
4.	I over-analyse situations to the point where it's unhelpful to me	1	2	3	4	5	6	7
5.	I struggle with my thoughts	1	2	3	4	5	6	7
6.	Even when I'm having upsetting thoughts, I can see that those thoughts may not be literally true	1	2	3	4	5	6	7
7.	I get upset with myself for having certain thoughts	1	2	3	4	5	6	7
8.	I need to control the thoughts that come into my head	1	2	3	4	5	6	7
9.	I find it easy to view my thoughts from a different perspective	1	2	3	4	5	6	7
10.	I tend to get very entangled in my thoughts	1	2	3	4	5	6	7
11.	I tend to react very strongly to my thoughts	1	2	3	4	5	6	7
12.	Its possible for me to have negative thoughts about myself and still know that I am an OK person	1	2	3	4	5	6	7
13.	It's such a struggle to let go of upsetting thoughts even when I know that letting go would be helpful	1	2	3	4	5	6	7

Thank you for completing this questionnaire

Appendix D

Information sheet for potential participants

Study Title: Exploring the Relationship Between Cognitive Fusion, Schema Modes and Eating Disorders

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

What is the purpose of the study? This research project aims to explore the relationship between eating disorder symptoms and two relatively new psychological models; Acceptance and Commitment Therapy and Schema Therapy. The aim of this research is improve understand of eating disorders.

Why have I been chosen? You have been chosen because you attend a specialist eating disorder service.

Do I have to take part it? No. Participation in this research project is entirely voluntary and not compulsory. Participation (or non-participation) will not affect your NHS treatment in any way. If you decide you would like to take part you will be asked to read this information sheet and to sign a consent form.

What will I have to do? If you agree to take part, you will be asked by the researcher to complete three questionnaires on one occassion. These questionnaires will look at your eating disorder symptoms, your schema modes which are moment to moment emotional states we all have to some degree and a measure of psychological flexibility. This research is interested in the relationship between these factors.

What will be done with the information I give? Any information that you provide will be treated with the strictest confidence. All information will be anonymised and will be held in a secure office in a locked filing cabinet in NHS Grampians outpatient eating disorder service. Your name will not be used on any of the information you provide and instead you will have a research code number to ensure confidentiality. Your personal details and research code will be kept secure so that you can withdraw at any time but only the chief investigator will have access to this document and it will be destroyed after the researchers thesis has been examined.

What are the possible disadvantages and risks of taking part? The disadvantages or risks of taking part are minimal. However, it is possible that some of the questions in the questionnaires may identify areas of difficulty or feelings that you had not considered before. If you require support and are attending the Eating Disorders Service you could speak to your clinician or ring the department on 01224 557392 and a therapist will be able to discuss any concerns that you have. If you are concerned about this or have any additional questions about participating in the study the researcher is more than happy to discuss this with you before deciding on your participation in the study. Independent advice can be found by telephoning the Eating Disorders Service on 01224 557392 where you can request to speak to a member of the team that is not directly involved in the research project. If you are no longer attending an NHS service and you do not want to speak to anyone within the NHS, the

University of Edinburgh or the researcher (details below) then you could contact Beating Eating Disorder's (BEAT's) helpline on 0845 634 1414.

What are the possible benefits of taking part? There is no individual benefit to taking part in this research. The information from this research project will aide our understanding of factors which may contribute to eating disorder symptoms. It will also allow us to explore the theoretical basis of two new psychological models.

What will happen to the results of the research study? The anonymised results of this research study will be written up and submitted as part fulfilment of the researcher's Doctorate in Clinical Psychology at the University of Edinburgh. The results of the research will also be disseminated through presentations to the outpatient Eating Disorders Service and other interested parties. It is also hoped that the results will be written up for a scientific article.

Will my taking part in the research be kept confidential?:All information which is collected during the course of the reasearch will be strictly confidential. Your questionnaires will be completely anonymous. Your consent form will be kept seperate from your questionnaires in a secure filing cabinet within NHS Grampian.

Who is organising and funding the research? This research is being funded my National Education Scotland.

Who has reviewed the research project? The project has been reviewed by the University of Edinburgh and the North of Scotland Research Ethics Service.

Complaints. If you have any concerns about any aspect of this study you should contact the researcher in the first instance who will do their best to answer any questions or queries that you may have. If you remain unsatisfied and wish to complain formally this can be done through the NHS complaints procedure or the University of Edinburgh, the details of which can be seen below.

Contact Details

NHS Grampian Complaints Team, Westholme, Woodend Hospital, Queens Road, Aberdeen, AB15 6LS, Telephone: 01224 556447

Matthias Schwannauer – Programme Director (D. Clin. Psychol.), School of Health in, Social Science, The University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG, Telephone: 0131 651 3972

Researcher: Samantha Masley, Trainee Clinical Psychologist, NHS Grampians Eating Disorder Service, Fulton Clinic, Royal Cornhill Hospital Aberdeen, AB252ZH, 01224 557392, email: samantha.masley@nhs.net.

Academic Supervisor: Dr David Gillanders, Clinical Psychologist and Depute Programme Director; The University of Edinburgh, david.gillanders@ed.ac.uk; Tel:0131 651 3946.

Beating Eating Disorders, (BEAT) Helpline; 0845 634 1414; help@b-eat.co.uk

Thank you for considering participation in this research

Appendix E

NHS Grampian

Dear ,

I am writing to inform you of some research that is currently being undertaken in our department. As you would be eligible to participate I have enclosed the information sheet for you to read. It is entirely your decision to participate or not and your decision will not influence your treatment in anyway. The research will have no direct benefit for you but it is hoped that it will enhance our understanding of eating disorders more generally.

If you would like to participate you will be given the opportunity to meet with Samantha Masley (the main researcher) who will answer any questions you have about the study. If you choose to take part you will be asked to complete a consent form and fill in three questionnaires on one occasion. Your responses on these questionnaires would be completely anonymous. In total, participation would take approximately 45 minutes of your time.

Next time we meet I will ask you about your thoughts on participating. Alternatively, if you would like to be considered you could contact the main researcher directly. You could email her at Samantha.masley@nhs.net or ring the department and leave her a message (01224 557392).

I look forward to seeing you soon

Yours sincerely

Appendix F

NHS Grampian

Dear,

I am writing to inform you of some research that is currently being undertaken in our department. As you would be eligible to participate I have enclosed the information sheet for you to read. It is entirely your decision to participate or not and your decision will not influence your treatment in anyway. The research will have no direct benefit for you but it is hoped that it will enhance our understanding of eating disorders more generally.

If you would like to participate you will be given the opportunity to meet with Samantha Masley (the main researcher) who will answer any questions you have about the study. If you choose to take part you will be asked to complete a consent form and fill in three questionnaires on one occasion. Your responses on these questionnaires would be completely anonymous. In total, participation would take approximately 45 minutes of your time.

If you would like to be considered you can contact the main researcher directly via email at Samantha.masley@nhs.net or ringing the department and leaving her a message (01224 557392).

Yours sincerely

Appendix G

Study Number: 11/S0801/4

Participant number:

NHS Board:

CONSENT FORM

Title of project: **Exploring the Relationship Between Cognitive Fusion, Schema Modes and Eating Disorders**

	Please Initial
1. I confirm that I have read and understand the information sheet dated the 14/02/11 (version 3.2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2. I understand my participation is voluntary and that I am free to withdraw at any time without giving any reasons, without my medical care or legal rights being affected.	☐
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from regulatory authorities or from the NHS Trust/Health Board, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
4. I agree to take part in the above study.	☐

_____	_____	_____
Name of participant	Date	Signature:
_____	_____	_____
Name of person taking consent (If different from the researcher)	Date	Signature:
_____	_____	_____
Researcher	Date	Signature:

Appendix H

NRES Committees - North of Scotland
Summerfield House
2 Eday Road
Aberdeen
AB15 6RE

Telephone: 01224 558474
Facsimile: 01224 558609
Email: nosres@nhs.net

NHS
Grampian

31 January 2011

Mrs Samantha Masley
Trainee Clinical Psychologist
Eating Disorders Service
Fulton Clinic
Royal Cornhill Hosptial
ABERDEEN
AB25 2ZH

nosres@nhs.net
FAO Rachel

Dear Mrs Masley

Study Title: **Exploring the Relationship Between Cognitive Fusion, Schema Modes and Eating Disorders**

REC reference number: **11/S0801/4**

The Research Ethics Committee reviewed the above application at the meeting held on 27 January 2011.

Documents reviewed

The documents reviewed at the meeting were:

Document	Version	Date
REC application	3.1	13 January 2011
Participant Information Sheet	3.1	14 December 2010
Protocol	3.1	14 December 2010
Summary Flowchart	3.1	16 December 2010
Referees or other scientific critique report		06 January 2011
Investigator CV	3.1	20 December 2010
Covering Letter		14 December 2010
Participant Consent Form	3.1	14 December 2010
Questionnaire: Eating Disorder - EDE -Q	3.1	20 December 2010
Questionnaire: SMI	3.1	20 December 2010
Questionnaire: CFQ13	3.1	20 December 2010
David Gillanders - CV	3.1	20 December 2010
Copy of Final Report	3.1	14 December 2010

Provisional opinion

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

It must be noted that full ethical approval for the study should not be assumed until you receive a final letter of approval.

The Committee delegated authority to confirm its final opinion on the application to the Ethics Co-ordinator.

Further information or clarification required

Thank you for attending the meeting and clarifying the following points:

- The Committee would like to confirm that any approval given is relevant to research in the United Kingdom and not Australia.

- The Committee asked for an overview of the study. You replied that the aim of the study was to correlate the severity of eating disorders with measures of schema modes and cognitive fusion which refer to beliefs in relation to eating disorders. Demonstrating a strong correlation between the two may potentially assist with the development of interventions for treatment of eating disorders.

- The Committee asked what you would do if there was only a small correlation, you replied that previous work carried out (unpublished data) did find a strong correlation between the two.

- The Committee asked what the primary outcome of the study was. You replied that each questionnaire would generate an outcome in its own right.

- You confirmed that the questionnaires were validated. The Committee wondered why the questionnaires could not be anonymous. You replied that you felt that everyone should have the right to withdraw from the research and your professional body and British Psychological Society encouraged this. The Committee felt that if participants did not want to take part, they have the choice not to do so and felt that participants would appreciate the fact that no identifiable information would be recorded about them if they did. The Committee strongly suggest that the questionnaires are anonymous.

- The Committee asked that a letter of invitation comes from the Clinician in charge of the patient's care, with contact details of the researcher, allowing the participant to opt-in to the study.

Participant Information Sheet

- The Committee asked that you use a standard participant information sheet and make the language more user-friendly. A standard participant information sheet is enclosed.

In addition, the Committee asked for the following points to be addressed:

Consent Form

- Please use a standard consent form. A copy is enclosed for your information.

When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates.

If the committee has asked for clarification or changes to any answers given in the application form, please do not submit a revised copy of the application form; these can be addressed in a covering letter to the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 31 May 2011.

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

11/S0801/4	**Please quote this number on all correspondence**

Yours sincerely

Professor Siladitya Bhattacharya
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments.

Copy to: Ms Gemma Watson
NHS Grampian R&D Department

North of Scotland Research Ethics Committee (1)

Attendance at Committee meeting on 27 January 2011

Committee Members:

Name	Profession	Present
Professor Siladitya Bhattacharya	Professor Reproductive Medicine	Yes
Professor Graham Devereux	Professor of Respiratory Medicine	Yes
Mrs Diane Fleming	Retired Clinical Trials Co-ordinator	Yes
Professor Helen Galley	Chair of Anaesthesia & Intensive Care	Yes
Dr Stuart Hannabuss	Lay Member - Research Associate	Yes
Ms Sue Harrison	Nurse	Yes
Mrs Kathryn McMullan	Pharmacist	Yes
Professor Graeme Murray	Professor of Pathology, Consultant Histopathologist, Head of Pathology	Yes
Mrs Jane Ormerod	Senior Nurse	Yes
Dr Detlev Rogahn	Consultant Paediatrician	Yes
Reverend Anthony Schmitz	Lay Member - Reverend	No
Mrs Sylvia Stephen	Lay Member - Human Nutrition Manager	Yes
Dr Berwyn Williams	Lay Member - Retired Principal Scientific Officer, Macaulay Institute	No

Also in attendance:

Name	Position (or reason for attending)
Miss Karen Gauld	Ethics Administrator
Dr Rachel Venables	Scientific Officer

NRES Committees - North of Scotland
Summerfield House
2 Eday Road
Aberdeen
AB15 6RE

Telephone: 01224 558474
Facsimile: 01224 558609
Email: nosres@nhs.net

NHS
Grampian

23 February 2011

Mrs Samantha Masley
Trainee Clinical Psychologist
NHS Grampian
Eating Disorders Service
Fulton Clinic
Royal Cornhill Hospital
ABERDEEN
AB25 2ZH

Dear Mrs Masley

Study Title: **Exploring the Relationship Between Cognitive Fusion, Schema Modes and Eating Disorders**

REC reference number: **11/S0801/4**

Thank you for your letter of 23 February 2011 responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered by the Scientific Officer.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised] subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Questionnaire: CFQ13	3.1	20 December 2010
Response to Request for Further Information		
REC application	3.1	13 January 2011
Questionnaire: Eating Disorder - EDE -Q	3.1	20 December 2010
Questionnaire: SMI	3.1	20 December 2010
Summary Flowchart	3.1	16 December 2010
Participant Information Sheet	3.2	14 February 2011
Protocol	3.1	14 December 2010
Clinicians Letter 1	3.2	18 February 2010
Referees or other scientific critique report		06 January 2011
Investigator CV	3.1	20 December 2010
Participant Consent Form	3.2	14 February 2011
Covering Letter		14 December 2010
Covering Letter		23 February 2011
David Gillanders - CV	3.1	20 December 2010
Copy of Final Report	3.1	14 December 2010
Clinicians Letter 2	3.2	18 February 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

11/S0801/4 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

PP RSBhattacharya

Professor Siladitya Bhattacharya
Chair

Enclosures: After ethical review – guidance for researchers

Copy to: Ms Gemma Watson
NHS Grampian R&D Department

Appendix I

Mr Angus Watson
Research & Development Director
NHS Highland Research & Development Office
Room S101
Centre for Health Science
Old Perth Road
Inverness
IV2 3JH

Tel: 01463 255822
Fax: 01463 255838
E-mail: angus.watson@nhs.net

NHS Highland

10 March 2011

NHS Highland R&D ID: **727**
NRSPCC ID: **NRS10/MH38**

Mrs Samantha Masley
Trainee Clinical Psychologist
NHS Grampian
Eating Disorders Service
Fulton Clinic
Royal Cornhill Hospital
Aberdeen
AB25 2ZH

Dear Mrs Masley,

Management Approval for Non-Commercial Research

I am pleased to tell you that you now have Management Approval for the research project entitled: **'Exploring the Relationship Between Cognitive Fusion, Schema Models and eating Disorders'.** I acknowledge that:

- The project is co-sponsored by the University of Edinburgh and NHS Lothian.
- The project does not require external funding.
- Research Ethics approval for the project has been obtained from the North of Scotland Research Ethics Committee, (Reference Number: 11/S0801/4).
- The project is Site-Specific Assessment exempt.

The following conditions apply:

- The responsibility for monitoring and auditing this project lies with the University of Edinburgh and NHS Lothian.

- This study will be subject to ongoing monitoring for Research Governance purposes and may be audited to ensure compliance with the Research Governance Framework for Health and Community Care in Scotland (2006, 2nd Edition), however prior written notice of audit will be given.
- NHS Highland resources used are limited to the time taken by local staff to identify potential participants as detailed in the R&D application form.
- **Mrs Masley requires a Letter of Access prior to starting the project at this site. This will be made available in the next few days.**
- All amendments (minor or substantial) to the protocol or to the REC application should be copied to the NHS Highland Research and Development Office together with a copy of the corresponding approval letter.
- The paperwork concerning all incidents, adverse events and serious adverse events, thought to be attributable to participant's involvement in this project should be copied to the NHS Highland R&D Office.

Please report the information detailed above, or any other changes in resources used, or staff involved in the project, to the NHS Highland Research and Development Manager, Frances Hines (01463 255822, frances.hines@nhs.net).

Yours sincerely,

Mr Angus Watson
NHS Highland Research and Development Director

cc Frances Hines, R&D Manager, NHS Highland Research & Development Office, Room S101, The Centre for Health Science, Old Perth Road, Inverness, IV2 3JH
Dr Julie Kelly, Scientific Advisor, North of Scotland Research Ethics, Summerfield House , 2 Eday Road , Aberdeen AB15 6RE.
Pamela Smith, Senior Administrator, NHS Research Scotland Coordinating Centre, Research & Development Office, Foresterhill House Annexe, Foresterhill, Aberdeen, AB25 2ZB

NHS
Tayside

15 March 2011

Mrs Samantha Masley
Trainee Clinical Psychologist
NHS Grampian
The Eating Disorder Service
Fulton Clinical
Royal Cornhill Hospital
ABERDEEN
AB25 2ZH

Dear Mrs Masley,

R & D MANAGEMENT APPROVAL - TAYSIDE

Title: Exploring the Relationship Between Cognitive Fusion, Schema Modes and Eating Disorders.

Chief Investigator: Mrs Samantha Masley **Principal Investigator: Mrs Samantha Masley**

Tayside Ref: 2011MH01 **NRS Ref: NRS10/MH38**

REC Ref: 11/S0801/4

EudraCT Ref: N/A **CTA Ref: N/A**

Sponsors: University of Edinburgh and NHS Lothian

Funder: Unfunded

Many thanks for your application to carry out the above project here in NHS Tayside. I am pleased to confirm that the project documentation (as outlined below) has been reviewed, registered and Management Approval has been granted for the study to proceed locally in Tayside.

Approval is granted on the following conditions:-

- ALL Research must be carried out in compliance with the Research Governance Framework for Health & Community Care, Health & Safety Regulations, data protection principles, statutory legislation and in accordance with Good Clinical Practice (GCP).
- All amendments to be notified to TASC R & D Office.
- All local researchers must hold either a Substantive Contract, Honorary Research Contract, Honorary Clinical Contract or Letter of Access with NHS Tayside where required (http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx).
- TASC R & D Office to be informed of change in Principal Investigator, Chief Investigator or any additional research personnel locally.

- Notification to TASC R & D Office of any change in funding.

- As custodian of the information collated during this research project you are responsible for ensuring the security of all personal information collected in line with NHS Scotland IT Security Policies, until destruction of this data.

- Recruitment numbers on a quarterly basis to be reported to TASC R & D Office.

- Annual reports are required to be submitted to TASC R & D Office with the first report due 12 months from date of issue of this management approval letter and at yearly intervals until completion of the study.

- Notification of early termination within 15 days or End of Trial within 90 days followed by End of Trial Report within 1 year to TASC R & D Office.

- You may be required to assist with and provide information in regard to audit and monitoring of study.

Please note you are required to adhere to the conditions, if not, NHS management approval may be withdrawn for the study.

Approved Documents

Document	Version	Date
IRAS SSI Form (67117/173821/6/115/81942/199964)		**14/12/10**
Ethics – Favourable Ethical Opinion Letter		**23/02/11**
IRAS REC Form (67117/173804/1/783)		**14/12/10**
IRAS R&D Form (67117/173814/14/565)		**14/12/10**
* Summary Flowchart	3.1	
Research Protocol	**3.1**	**14/12/10**
CV – Samantha Masley		**17/12/10**
CV – David Gillanders		
PIS	**3.2**	**14/02/11**
Consent Form	**3.2**	**14/02/11**
* Clinicians Letter 1	3.2	18/02/11
Clinicians Letter 2	**3.2**	**18/02/11**
* SMI (Version 1.1)		
* EDE-Q		
* CFQ13		
NOSRES Peer Review Form		
* Copy of Final Report		

* Summary Flowchart – Version 3.1 provided to R&D. Version 3.1 dated 16/12/10 on the favourable ethical opinion letter.
* Clinicians Letter 1 – Version 3.2 dated 18/02/11 provided to R&D. Version 3.2 dated 18/02/10 on the favourable ethical opinion letter.
* SMI, EDE-Q and CFQ13 – No version number or date provided to R&D. Version 3.1 dated 20/12/10 on the favourable ethical opinion letter.
* Copy of Final Report - No version number or date provided to R&D. Version 3.1 dated 14/12/10 on the favourable ethical opinion letter.

May I take this opportunity to wish you every success with your project.

Please do not hesitate to contact TASC R & D Office should you require further assistance.

Yours sincerely,

Elizabeth Coote
R&D Manager

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Date 09/03/11
Our Ref 2010PC016

Enquiries to
Extension 51121
Direct Line 01224

551121

Dear Mrs Masley

Management Approval for Non-Commercial Research

REC Ref: **11/S0801/4**
NRS Ref: **NRS10/MH38**
Project title: **Exploring the Relationship Between Cognitive Fusion, Schema Modes and Eating Disorders**

Thank you very much for sending all relevant documentation. I am pleased to confirm that the above project is now registered with the NHS Grampian Research & Development Office. The project now has R & D Management Approval to proceed locally. This is based on the documents received from yourself and the relevant Approvals being in place.

All research with an NHS element is subject to the Research Governance Framework for Health and Community Care (2006, 2nd edition), and as Chief or Principal Investigator you should be fully committed to your responsibilities associated with this.

It is particularly important that you inform us when the study terminates.

The R&D Office must be notified immediately and any relevant documents forwarded to us if any of the following occur:

- A change of Principal Investigator, Chief Investigator or any additional research personnel
- Premature project termination
- Any amendments (particularly a study extension)
- Any change to funding or any additional funding

We hope the project goes well, and if you need any help or advice relating to your R&D Management Approval, please do not hesitate to contact the office.

Yours sincerely

Susan Ridge
Business Development Officer

Cc: NHS Research Scotland Permissions Co-ordinating Centre (NRS Permissions CC)

Appendix J

Instructions for Authors
International Journal of Eating Disorders

Submission

To submit your manuscript online, please:

Prepare your manuscript and illustrations in appropriate format, according to the instructions given here.

If you have not already done so, create an account for yourself in the system at the submission site, http://mc.manuscriptcentral.com/ijed/ by clicking on the "Create an Account" button. To monitor the progress of your manuscript throughout the review process, just log in periodically and check your Author Center.

Please be sure to study the Instructions and Forms given at the site carefully, and then let the system guide you through the submission process. Online help is available to you at all times during the process. You are also able to exit/re-enter at any stage before finally "submitting" your work. All submissions are kept strictly confidential. If you have any questions, do not hesitate to contact us at support@scholarone.com .

No article can be published unless accompanied by a signed publication agreement, which serves as a transfer of copyright from author to publisher. A copy of the agreement, executed and signed by the author, is required with each manuscript submission. (If the article is a "work made for hire," the agreement must be signed by the employer.) A publication agreement may be obtained from the editor or the publisher. A copy of the publication agreement appears in most issues of the journal. Only original papers will be accepted and copyright in published papers will be vested in the publisher. It is the author's responsibility to obtain written permission to reproduce material that has appeared in another publication.

Manuscripts are received by the editorial office with the understanding that they represent original works, have not published previously, and are not under simultaneous review by another publication. If parts of the manuscripts have been presented at a scientific meeting, this should be indicated on the title page.

Manuscripts are evaluated by one to three members of the Editorial Board, or outside reviewers selected by the Editor. Accepted manuscripts become the permanent property of The International Journal of Eating Disorders and cannot be printed elsewhere without prior permission of the publisher.

Preparation of Manuscript

Number all pages of the manuscript except the figures (including title page and abstract) consecutively. Parts of the manuscripts should be arranged in the following sequence:

(1) Title page. (numbered 1) should include the full names, titles, and affiliations of all authors, and an abbreviated title (Running Head) that should not exceed 50 characters, counting letters, spacing, and punctuation. This Running Head should be typed in upper case letters centered at the bottom of the title page. Each page of the manuscript (excluding figures) should be identified by typing the first two or three words of the full title in the upper right-hand corner above the page number.

(2) Abstract. (150-word maximum) should be started on a separate page, numbered 2. Type the word "Abstract" in upper and lower case letters, centered at the top of page 2. Authors of articles submitted to the Journal involving research data or reviews of the literature must now include the following information in the form of a structured abstract, under the headings indicated. The abstract should be typed as a single paragraph on one page: **Objective:** briefly indicate the primary purpose of the article, or major question addressed in the study. **Method:** indicate the sources of data, give brief overview of methodology, or, if review article, how the literature was searched and articles selected for discussion. For research based articles, this section should briefly note study design, how subjects were selected, and major outcome measures. **Results:** summarize the major or key findings. Discussion**:** indicate main clinical,

theoretical, or research applications/implications. The *Journal* will continue to use unstructured abstracts for case reports.

(3) Text. Begin the text on page 3 and be sure to identify each page with the short title typed in the upper right-hand corner above the page number. Type the full title of the manuscript centered at the top, and then begin the text. The full title appears on page 3 only. Indent all paragraphs. While there is no maximum length for article submissions it is advisable that research be conveyed as concisely as possible.

(4) References. Begin on separate page, with the word "References" typed in upper and lower case letters, centered at the top of the page.

(5) Appendixes. Typed each appendix on a separate page labeled "Appendix A, B", etc., in the order in which they are mentioned in the text.

(6) Footnotes. Start on separate page.

(7) Tables. Tables should be double-spaced, including all headings, and should have a descriptive title. If a table extends to another page, so should all titles and headings. Each table should be numbered sequentially in Arabic numerals and begin on a new page. Be sure to explain abbreviations in tables even if they have already been explained in-text. Consider the tables and figures to be self-contained and independent of the text. They should be interpretable as stand-alone entities.

(8) Figure captions. Start on separate page. Each figure caption should have a brief title that describes the entire figure without citing specific panels, followed by a description of each panel. Figure captions should be included in the submitted manuscript as a separate section. Be sure to explain abbreviations in figures even if they have already been explained in-text. Consider the tables and figures to be self-contained and independent of the text. They should be interpretable as stand-alone entities. Axes for figures must be labeled with appropriate units of measurement and description.

Manuscript Form and Presentation

All manuscripts are subject to copyediting, although it is the primary responsibility of the authors to proofread thoroughly and insure correct spelling and punctuation, completeness and accuracy of references, clarity of expression, thoughtful construction of sentences, and legible appearance prior to the manuscript's submission. Preferred spelling follows *Webster's New Collegiate Dictionary* or *Webster's Third New International Dictionary* . The manuscript should conform to accepted English usage and syntax.

Microsoft Word is the preferred format for the creation of your text and tables (one file with tables on separate pages at the end of your text). Refrain from complex formatting; the Publisher will style your manuscript according to the Journal design specifications. Do not use desktop publishing software such as Aldus PageMaker or Quark XPress.

Use headings to indicate the manuscript's general organization. Do not use a heading for the introduction. In general, manuscripts will contain one of several levels of headings. Centered upper case headings are reserved for Methods, Results, and Discussion sections of the manuscript. Subordinate headings (e.g., the Subjects or Procedure subsection of Methods) are typed flush left, underlined, in upper case and lower case letters. The text begins a new paragraph.

Presenting statistical data in text: For additional detail regarding statistical requirements for the manuscript see IJED Statistical Formatting Requirements. For more detailed background information on statistical analyses and their rationale authors are referred to IJED Statistical Reporting Guidelines.

Referencing in the text. Wiley's Journal Styles Are Now in EndNote (Wiley's Journal Styles and EndNote) . EndNote is a software product that we recommend to our journal authors to help simplify and streamline the research process. Using EndNote's bibliographic management tools, you can search bibliographic databases, build and organize your reference collection, and

then instantly output your bibliography in any Wiley journal style. If you already use EndNote, you can download the reference style for this journal. To learn more about EndNote, or to purchase your own copy, click here . If you need assistance using EndNote, contact endnote@isiresearchsoft.com , or visit www.endnote.com/support

Referencing follows the Vancouver method of reference citation. In this system, references are numbered consequtively in the order in which they are first mentioned in the text. Indentify each reference in text, tables, and legends by Arabic numbers. All references cited should be listed numerically at the end of the paper. Prepare citations according to the style used in Index Medicus and the International list of periodical title word abbreviations (ISO 833).

All reference citations in the text should appear in the reference list. When there are less than seven authors, each must be listed in the citation. When seven or more authors, list the first six followed by et al. after the name of the sixth author. Representative examples are as follows:
Journal Article: 1. Endicott J, Spitzer RL. A diagnostic interview: The schedule for affective disorders and schizophrenia. Arch Gen Psychiatry 1978;35:837-844.

Book Chapter: 2. Fairburn CG, Cooper Z. The eating disorders examination (12th ed). In: Fairburn CG, Wilson GT, editors. Binge eating: nature, assessment, and treatment. New York: The Guilford Press, 1993, p. 317-331.

Book: 3. Tudor I. Learner-centeredness as language education. Cambridge: Cambridge University Press; 1996.

Preparation of figures. To ensure the highest quality print production, your figures must be submitted in TIFF format according to the following minimum resolutions:

- 1200 dpi (dots per inch) for black and white line art (simple bar graphs, charts, etc.)
- 300 dpi for halftones (black and white photographs)
- 600 dpi for combination halftones (photographs that also contain line art such as labeling or thin lines)

Vector-based figures (usually created in Adobe Illustrator) should be submitted as EPS. Do not submit figures in the following formats:JPEG,GIF,Word, Excel, Lotus1-2-3, PowerPoint, PDF. Graphs must show an appropriate grid scale. Each axis must be labeled with both the quantity measured and the unit of measurement. Color figures must be submitted in a CMYK colorspace. Do not submit files as RGB. All color figures will be reproduced in full color in the online edition of the journal at no cost to authors. Authors are requested to pay the cost of reproducing color figures in print. Authors are encouraged to submit color illustrations that highlight the text and convey essential scientific information. For best reproduction, bright, clear colors should be used.
Supplementary materials. Supplementary materials will be made available to readers as a link to the corresponding articles on the journal's website.

PROPOSED ADDITIONAL GUIDELINES FOR COPYEDITING OF MANUSCRIPTS FOR INTERNATIONAL JOURNAL OF EATING DISORDERS

The *Journal* Editor and Associate Editors propose additional guidelines for manuscript copyediting in order to enhance consistency in the organization of printed material, and to bring *IJED* style in line with other major scientific publications. The key elements follow.

1. Each structured abstract should consistently use these subheadings (at present, the headings vary somewhat from article to article): Objective, Method, Results, Discussion.

2. Many of our Authors use terms such as "anorexics" or "bulimics" as personal pronouns, referring to groups of individuals by their common diagnosis. Henceforth, these terms should be replaced with more neutral language, as for example: "individuals with anorexia nervosa", "patients with bulimia nervosa", or "participants with eating disorders".

3. In the Methods section, the subheading "Subjects" should now be replaced with the subheading "Participants", and this term should be used in place of "subjects" throughout the text.

4. Standard rules will continue to govern the use of capitalization in Headings and Subheadings. However, when a minor word in a Heading or Subheading actually has special or unique meaning, the rule should be overridden.

5. When referring to gender, "males and "females" should be used in cases where the study samples include both children (below age 18) and adults; when the participants comprise adults only, the terms "men" and "women" should be used. In articles that refer to children (i.e., below the age of 13), "boys" and "girls" should be used.

6. In articles that refer to genetic material, the names of genes should be spelled out in full the first time they appear in the text, after which an italicized abbreviation can be substituted.

7. The word "data" is plural so text should follow accordingly; for example, "The data show… the data are … the data were".

8. When an article references another article that appears in the very same issue of the *Journal* , (such occurrences are most likely in Special Issues), the citation will be updated by the copyeditor (i.e., volume number and pagination will be substituted for "in press").

9. For information on how to present *p* values and other standard measurements see IJED Statistical Formatting Requirements.

10. The Methods section should include a statement that the research was reviewed and approved by an institutional review board.

Proofs

Authors will be supplied with proofs to check the accuracy of typesetting. Authors may be charged for any alterations to the proofs beyond those needed to correct typesetting errors. Proofs must be checked and returned within 48 hours of receipt.
A *reprint order* form will be sent to the corresponding author along with the proofs. Those wishing to order reprints must return this form with payment when returning their corrected proof. Reprints are normally shipped 6-8 weeks after publication of the issue in which the item appears.

Appendix K

Instructions for Authors

Journal of Cognitive Behaviour Therapy

PREPARING FOR SUBMISSION

When submitting a paper, the author should always make a full statement to the editors about all submissions and previous reports that might be regarded as duplicate publication of the same or very similar work. If accepted the manuscript should not be republished in any other journal without the editors' and publisher's written consent. The manuscript should be accompanied by a covering letter from the corresponding author, stating that the manuscript has been seen and approved by all authors.

SUBMISSION OF MANUSCRIPTS

Language

All manuscripts must be in English. Writing should be concise and correct. English or American spelling is accepted if used consistently throughout the manuscript.

Electronic manuscripts

The editors encourage submission of electronic manuscripts whenever possible. All submissions should be made online at the ***Cognitive Behaviour Therapy*** ScholarOne Manuscripts site . New users should first create an account. Once a user is logged onto the site submissions should be made via the Author Centre.

The electronic manuscript should be accompanied by a covering letter as described above along with a clear indication of the computer platform and version of word processing system used. Please use this simple guideline for preparing your electronic manuscript:

1. Be consistent. The same elements should be keyed in exactly the same way throughout the manuscript.
2. Do not break words at the end of lines. Use a hyphen only to hyphenate compound words.
3. Enter only one space after the full-stop at the end of a sentence.
4. When emphasising words please use the italic feature of your word processor software.
5. Do not justify your text; use a ragged right-hand margin.
6. Use a double hyphen (--) to indicate a dash in text.
7. Do not use the lowercase l for 1 (one) or the uppercase O for 0 (zero).
8. The space bar should only be used as a word separator. Use TAB when identifying paragraphs or separating columns in tables.

Please observe that the Editorial offices and Taylor & Francis can receive files from many word processing systems; however, *styled Microsoft Word files* are preferred.

Keep ***illustrations*** as separate files. Supply correctly sized composite PDFs supported by hard copy. For colour illustrations the colour must be CMYK, not RGB. All fonts must be embedded, and the resolution of images should be of a quality suitable for printing. Files downloaded from web pages are not suitable, they will look ok on screen but not when printed. Do not use colour files if black and white only output is required.

Manuscript style

The 6th edition of the APA manual should be consulted. Be sure that the reference list is complete and accurate. Also make sure that statistical material follows the guidelines of the manual www.apastyle.org

Double-space the entire manuscript -- even the reference list -- and leave an all around margin of 1 inch or 2,5 cm. The ***Title page*** should include: 1) A brief but informative title, 2) First name, middle initial and surname of each author, 3) institution(s) to which the author(s) are affiliated, 4) full name and address, including telephone, fax and e-mail address, of the corresponding author, 5) word count including number of tables and figures (see below for word equivalent approximations) but excluding title pages and abstract.

Page 2 should carry the title only. ***Page 3*** should include an abstract, not exceeding 250 words, stating the purpose of the study, methods and main results. List up to five key words (avoid words already used in the title).

Organise the ***Main text*** under the following headings if possible: *Introduction, Methods, Results, Discussion, Acknowledgements and References* .

Figures, figure captions and tables should be printed on separate pages.

Figures and Illustrations.

We welcome figures sent electronically, but care and attention to these guidelines are essential as importing graphics packages can often be problematic.

1. Figures must be saved individually and separate to text. Please do not embed figures in the paper file.
2. Avoid the use of colour and tints for purely aesthetic reasons.
3. Figures should be produced as near to the finished size as possible.
4. All figures must be numbered in the order in which they appear in the paper (e.g. figure 1, figure 2). In multi-part figures, each part should be labelled (e.g. figure 1(a), figure 1(b)).
5. Figure captions must be saved separately, as part of the file containing the complete text of the paper, and numbered correspondingly.
6. The filename for the graphic should be descriptive of the graphic, e.g. Figure1, Figure2a.
7. Files should be saved as one of the following formats: TIFF (tagged image file format), PostScript or EPS (encapsulated PostScript), and should contain all the necessary font information and the source file of the application (e.g. CorelDraw/Mac, CorelDraw/PC).

Please note that it is in the author's interest to provide the highest quality figure format possible. Please do not hesitate to contact our Production Department if you have any queries.

Length of manuscript

Manuscripts for case studies and brief reports should not exceed six double spaced manuscript pages, inclusive of text, references, tables, and figures (approximately 2000 words). Regular articles should not exceed 5500 words. Theoretical and review articles should not exceed 8000 words. As a guideline, tables and figures approximate 150 words of text.

substantially from a copyrighted source). For further information and FAQs, please see http://journalauthors.tandf.co.uk/preparation/permission.asp .

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Appendix L

SIGN

Scottish Intercollegiate Guidelines Network

NHS Quality Improvement Scotland

50

SIGN 50

A guideline developer's handbook

Revised edition

January 2008

NHS Quality Improvement Scotland (NHS QIS) is committed to equality and diversity. This guideline has been assessed for its likely impact on the six equality groups defined by age, disability, gender, race, religion/belief, and sexual orientation.

For the full equality and diversity impact assessment report please see the "published guidelines" section of the SIGN website at **www.sign.ac.uk/guidelines/published/numlist.html**. The full report in paper form and/or alternative format is available on request from the NHS QIS Equality and Diversity Officer.

Scottish Intercollegiate Guidelines Network

SIGN 50

A guideline developer's handbook

January 2008

ISBN 978 1 905813 25 4
First published 2008

Scottish Intercollegiate Guidelines Network
Elliott House, 8 -10 Hillside Crescent
Edinburgh EH7 5EA

www.sign.ac.uk

Contents

Meeting the agree appraisal criteria

SIGN methodology complies with the criteria used by the AGREE (Appraisal of Guidelines for Research and Evaluation in Europe) to identify good quality guidelines. The chapters of this manual that describe how SIGN addresses each criterion are identified below.

		SIGN 50 chapter
Scope and purpose		
1.	The overall objective(s) of the guideline should be specifically described.	9.1
2.	The clinical question(s) covered by the guideline should be specifically described.	6.3
3.	The patients to whom the guideline is meant to apply should be specifically described.	9.1
Stakeholder involvement		
4.	The guideline development group should include individuals from all the relevant professional groups.	5
5.	The patients' views and preferences should be sought.	4
Rigour of development		
6.	Systematic methods should be used to search for evidence.	6
7.	The criteria for selecting the evidence should be clearly described.	6.3, 6.4
8.	The methods used for formulating the recommendations should be clearly described.	7.1
9.	The health benefits, side effects and risks should be considered in formulating the recommendations.	7.2
10.	There should be an explicit link between the recommendations and the supporting evidence.	7.2
11.	The guideline should be externally reviewed by experts prior to publication.	8.2
12.	A procedure for updating the guideline should be provided.	3.4
Clarity of presentation		
13.	The recommendations should be specific and unambiguous.	9.1
14.	The different options for diagnosis and/or treatment of the condition should be clearly presented.	9.1
15.	Key recommendations should be easily identifiable.	7.2.3
Applicability		
16.	The target users of the guideline should be clearly defined.	9.1
17.	The potential organisational barriers in applying the recommendations should be discussed.	10
18.	The potential cost implications of applying the recommendations should be considered.	7.4
19.	The guideline should be supported with tools for application.	10
20.	The guideline should present key review criteria for monitoring and audit purposes	9.1, 9.7
21.	The guideline should be piloted among end users.	8.1
Editorial independence		
22.	The guideline should be editorially independent from the funding body.	1.1
23.	Conflicts of interest of guideline development members should be recorded.	2.4

1 Introduction

1.1 CLINICAL GUIDELINES AND SIGN

The Scottish Intercollegiate Guidelines Network (SIGN) was established in 1993 by the Academy of Royal Colleges and their Faculties in Scotland, to develop evidence based clinical guidelines for the National Health Service in Scotland.[1,2] Since January 2005, SIGN has been part of NHS Quality Improvement Scotland, though under the transfer agreement with the Academy SIGN retains editorial independence in relation to the guidelines it produces.

Clinical practice guidelines have been defined as "*systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances*".[3] They are designed to help practitioners assimilate, evaluate and implement the ever increasing amount of evidence and opinion on best current practice. Clinical guidelines are intended as neither cookbook nor textbook but, where there is evidence of variation in practice which affects patient outcomes and a strong research base providing evidence of effective practice, guidelines can assist healthcare professionals in making decisions about appropriate and effective care for their patients.

The accepted criteria for validity of guidelines have evolved from the 'essential elements of good guidelines' identified by the US Institute of Medicine in 1990.[3] These recommended 'attributes of good guidelines' included validity, reliability, clinical applicability, clinical flexibility, clarity, multidisciplinary process, scheduled review, and documentation. The recommendations were underpinned by the twin themes of credibility and accountability: "*The link between a set of guidelines and the scientific evidence must be explicit, and scientific and clinical evidence should take precedence over expert judgement.*" SIGN's original Criteria for Appraisal of Clinical Guidelines for National Use,[4] and the more recent AGREE (Appraisal of Guidelines, Research and Evaluation for Europe) guideline appraisal instrument[5] are based on these founding principles of guideline development.

The AGREE criteria are reproduced in the introductory material to this manual, with links to those manual chapters that explain how SIGN addresses each criterion. The only area where SIGN does not comply with the AGREE criteria is in relation to the piloting of guidelines. The full appraisal instrument can be downloaded from the AGREE website: **www.agreetrust.org**

1.2 AIM AND STRUCTURE OF THIS MANUAL

This is the third revision of SIGN 50, previous versions having been issued in 2002 and 2004. SIGN methodology has continued to develop and since the previous version of this manual there have been significant developments in the procedures for reviewing guidelines, the involvement of patients and carers, and extending the range of evidence considered.

The principal aim of this manual is to provide a reference tool that may be used by individual members of guideline development groups as they work through the development process. Guidelines are intended for use by healthcare practitioners who are inevitably busy, with limited time available to read publications such as guidelines. Rather than overload every guideline with methodological details, SIGN 50 outlines the key elements of the development process common to all SIGN guidelines. Only where aspects of the topic under consideration require a variation from the standard process will these be reported in the guidelines themselves.

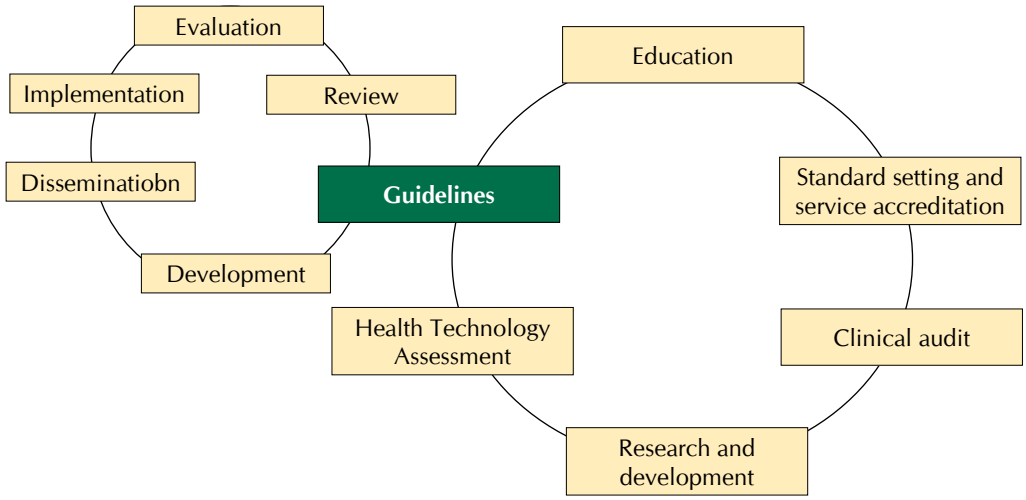
Guideline developers have an increasing obligation to be transparent about the methods they have used to develop their guideline. A secondary aim of this manual is to allow users to see how SIGN guidelines are developed, and instil confidence that the potential biases of guideline development have been addressed adequately, and that the recommendations are both internally and externally valid, and feasible for practice.

SIGN 50 is structured to follow the guideline development process from beginning to end, taking each step in turn. It starts with the context of guideline development in Scotland, and progresses from first proposal of a new topic to final publication and implementation of the guideline. Hyperlinks are provided in the text to guide the user to related topics where there is overlap between different chapters.

1.3 GUIDELINES IN CONTEXT

Guideline development, implementation, and review should be seen not as a linear process, but as a cycle of interdependent activities. These in turn are part of a range of complementary activities to translate evidence into practice, set and monitor standards, and promote clinical excellence in NHSiS, as illustrated in Figure 1.

Figure 1: Guideline and audit cycles



Guidelines frequently look at medicines, interventions and technologies that are also the subject of individual review with authorities responsible for approving their use in the NHS. In this respect SIGN takes account of the reviews carried out by the Scottish Medicines Consortium (SMC) and the National Institute for Health and Clinical Excellence (NICE). The close relationship between SIGN and other parts of NHS Quality Improvement Scotland facilitates these processes. The highest standards of patient care and improved outcomes are the ultimate goal.

Guidelines can achieve better treatment outcomes and care for patients, but local ownership of the implementation process is crucial to success in changing practice. For this reason, SIGN is responsible for the development of national guidelines and their implementability, but not directly for their implementation into practice. This is a responsibility of each individual NHS Board, and is now reinforced by the twin 'levers' of clinical governance and the standard setting and review components of NHS Quality Improvement Scotland. However, there is a role for national facilitation of local guideline implementation activities, and this is discussed in **Chapter 10.**

Links with local and national audit projects are also an essential part of guideline implementation, and SIGN has been working closely with the Information and Statistics Division (ISD) to develop the audit component of guidelines and, where possible, to develop minimum datasets to facilitate prospective audit. This is discussed in **Chapter 9.**

1.4 MEDICO-LEGAL IMPLICATIONS OF SIGN GUIDELINES

The potential medico-legal implications of clinical guidelines have been of ongoing concern to medical practitioners since the establishment of a Scottish national guideline development programme was first proposed. Dr Pamela Abernethy of Simpson and Marwick WS, one of the leading Scottish experts on medical negligence, provided an initial paper on the legal implications of guidelines to SIGN and NHS Scotland in December 1995.[6] In this paper she concluded that clinical guidelines do not rob clinicians of their freedom, nor relieve them of their responsibility to make appropriate decisions based on their own experience and according to the particular circumstances of each patient. It is stressed that the standard of care required by law derives from customary and accepted practice rather than from the imposition of practices through clinical guidelines.

Dr Abernethy refers to the 1955 case of Hunter v Hanley as establishing the standard of care required under Scottish Law and describes the three-step test used to establish the liability of a healthcare professional where it is alleged that (s)he has deviated from normal practice. The Central Legal Office (CLO) advised SIGN in 2006[7] that the Hunter v Hanley test is still the appropriate test in Scotland for liability for clinical negligence, ie it must be established that the course the healthcare professional has adopted "is one which no professional man of ordinary skill would have taken if he had been acting with ordinary care". This test was developed further by the Bolam test, ie a healthcare professional is not guilty of negligence if "he has acted in accordance with a practice accepted as proper by a responsible body of men skilled in that particular art". A healthcare professional may therefore defend a charge of negligence with evidence that (s)he acted in conformity with the practice accepted by another body of opinion. The test applied by the Court is therefore based on what is actually done in practice rather than on a prescription of what should be done as proposed by guidelines.

Dr Abernethy states also that customary and accepted practice will be established in court by introduction of expert testimony. Although clinical guidelines will not be introduced as a substitute for expert testimony, they may be referred to by an expert witness as evidence of such customary and accepted practice. The CLO has advised SIGN that this is still the case.

The Hunter v Hanley test has been developed since 1995 by the 1997 case of Bolitho v City and Hackney Health Authority. This case introduced a more critical approach to the evidence supplied by expert witnesses and provided that where it can be demonstrated that professional opinion is not capable of withstanding logical analysis, the judge would be entitled to determine that the opinion was not reasonable or responsible.

The CLO advice to SIGN following this case is that the opinions of medical experts may not be regarded as final and authoritative.[7] Although a defendant may present expert opinion that his practice was sound, the judge may look at additional evidence to determine whether the practice was in fact logical. It may be that evidence based guidelines will be referred to as part of that additional evidence and the court may require to know why such guidelines were not followed and the reasoning behind the decision not to follow them. There is consequently greater potential for clinical guidelines to have a greater role in identifying the standard of care.

In addition to this legal development in the determination of the duty of care, the origins of some guidelines which have been produced since 1995 may be relevant in the future in determining their legal status. There is an argument that some guidelines produced by organisations such as SIGN and NICE could come to be regarded as authoritative guidance in view of the robust methods used in their production and also in view of the national status of these organisations.

Some established national guidelines may be referred to by the court at present as a starting point from which to consider a healthcare professional's conduct. The Hunter v Hanley test does of course still apply in determining the standard of care and at present such guidelines do not set the standard of care. (This is stated in each SIGN guideline).

If the law were to develop in the future to accredit a more authoritative status to guidelines of this nature, the burden of proof, in the opinion of some commentators, may move to the healthcare professional where such a guideline is not adhered to. Instead of the plaintiff being required to prove that the healthcare professional failed to provide a minimum standard of care in accordance with the Hunter v Hanley Test, the healthcare professional may be required to prove that the care met the required standard of the Hunter v Hanley test although the guideline has not been applied. This is, however, only conjecture and at present the burden of proof remains with the plaintiff.

The CLO has advised SIGN that there has to date been no reference to SIGN guidelines in any reported cases of medical negligence.[7]

It is important to emphasise that SIGN guidelines are intended as an aid to clinical judgement not to replace it. Guidelines do not provide the answers to every clinical question, nor guarantee a successful outcome in every case. The ultimate decision about a particular clinical procedure or treatment will always depend on each individual patient's condition, circumstances and wishes, and the clinical judgement of the healthcare team.

Guidelines are, however, intended to address variation in practice. While there is no compulsion to implement any SIGN guideline or individual recommendations, NHS Boards, clinical teams, and individual practitioners in primary and secondary care should all be able to define the standard of care which they provide, and to justify if necessary why these do not meet nationally agreed recommendations.

1.5 REVIEW AND UPDATING OF THIS MANUAL

It is intended that *SIGN 50* should be a 'living' publication, continually revised to reflect future developments in SIGN methodology. For this reason the definitive version of this handbook is that published on the SIGN website. Printed versions are produced for use as required by SIGN guideline development groups.

Comments on either content or presentation of this document are welcome and should be sent to the SIGN Executive, Elliott House, 8 -10 Hillside Crescent, Edinburgh EH7 5EA. Email: **sign@sign.ac.uk**

2 Organisation of guideline development

2.1 THE SCOTTISH INTERCOLLEGIATE GUIDELINES NETWORK

The Scottish Intercollegiate Guidelines Network (SIGN) was established in 1993 by the Conference (later, the Academy) of Royal Colleges and their Faculties in Scotland, to develop evidence based clinical guidelines for the National Health Service in Scotland.[2] This followed the publication of a report by the Clinical Resource and Audit Group (CRAG) which highlighted the need for national, evidence based clinical guidelines to be developed by "the Royal Colleges, the specialist associations of the healthcare professionals and relevant educational bodies".[1]

SIGN has evolved significantly since 1993 but remains a collaborative initiative - a network of clinicians, patients' representatives and other healthcare professionals, including all the medical specialties, nursing, pharmacy, dentistry, professions allied to medicine, and NHS management. Patients are represented on SIGN by Voluntary Health Scotland and lay representation. The current membership of SIGN Council is noted on the website: **www.sign.ac.uk**

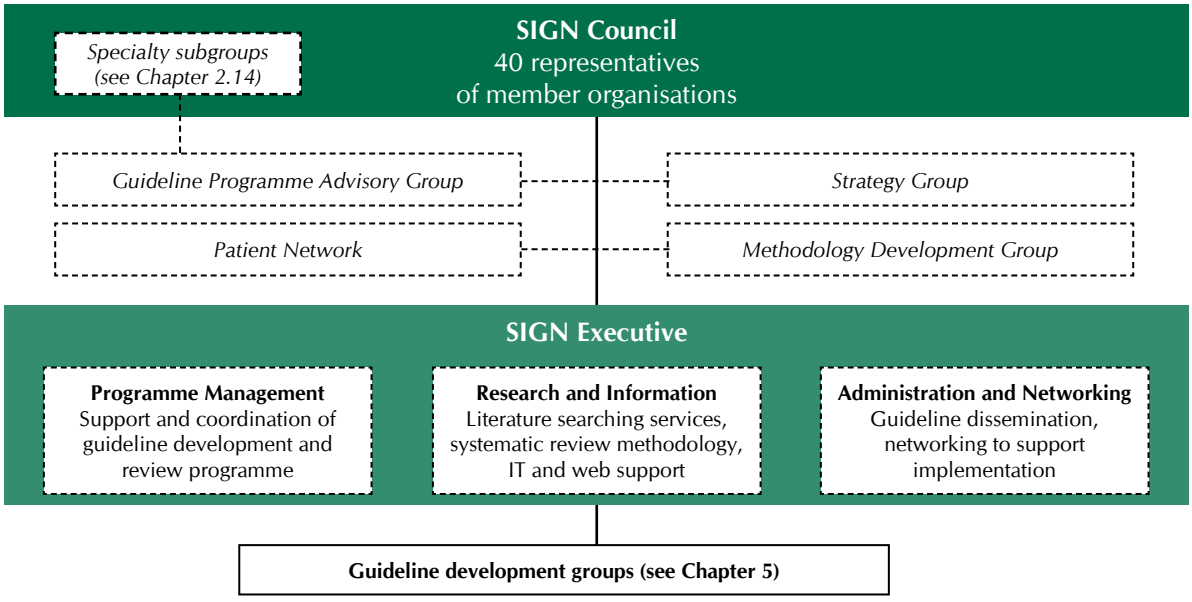
2.1.1 SIGN COUNCIL

SIGN Council is the policy making body for SIGN with overall responsibility for topic selection, methodology, and editorial policy. Members of SIGN Council are nominated by a particular Royal College or other professional organisation or committee, but also represent their specialty or discipline in a wider sense and consult widely with other specialist societies in their field. SIGN also works closely with other parts of its parent body, NHS Quality Improvement Scotland, as well as other relevant national groupings and agencies within NHSScotland.

Members of SIGN Council determine the overall direction of SIGN's development and play a key role in shaping the SIGN guideline programme. Some are also actively involved in aspects of the guideline development process - as members of Advisory Groups, or on the editorial group for specific guidelines, or as chairs or members of individual guideline development groups - and all provide input into the selection of topics for guideline development and the composition of guideline development groups **(see Chapters 4 and 5).**

The structure of SIGN is illustrated in Figure 2

Figure 2 STRUCTURE OF SIGN



2.1.2 STRATEGY GROUP

The Strategy Group is chaired by the Vice-Chair of SIGN Council and provides a strategic monitoring and advisory role for SIGN. Among the specific functions of the group are:

- To discuss and develop emerging strategies for SIGN to be presented to SIGN Council
- To advise on the development of SIGN's business plan
- To monitor SIGN's performance in relation to the business plan
- To discuss relevant issues raised by SIGN Council or the SIGN Executive and advise on actions to be taken.

Membership of the group is made up of five elected voting members of SIGN Council, (one of whom must be a lay representative and at least two current holders of medical or dental qualifications and are members of Royal Colleges or their Faculties in Scotland) plus representation from other parts NHS Quality Improvement Scotland. Meetings are also attended by the Chair of SIGN, Executive Secretary to SIGN Council, and members of the SIGN Senior Management Team.

2.1.3 GUIDELINE PROGRAMME ADVISORY GROUP (GPAG)

GPAG oversees the guideline development programme. Specific functions include:

- Monitoring progress of the programme
- Advising the SIGN Executive regarding any concerns they may have with the development of specific guidelines
- Directing SIGN Council specialty subgroups as they seek nominations for new topics
- Selecting appropriate proposals for new topics for discussion by Council from the full list of proposals submitted to the SIGN Executive.

Membership of the group consists of:

- Programme Director (Chair)
- Chair of SIGN Council (ex-officio)
- Director (ex officio)
- A child health representative on SIGN Council
- A General Practice representative on SIGN Council
- Leads of the SIGN Council specialty subgroups
- A nursing representative on SIGN Council
- The pharmaceutical representative on SIGN Council
- A representative of the other parts of NHS Quality Improvement Scotland.

Meetings are also attended by the Executive Secretary to SIGN Council.

2.1.4 SPECIALTY SUBGROUPS (SSGS)

There are five specialty subgroups of SIGN Council, one in each of the NHS priority areas (cancer, children, cardiovascular disease, mental health) plus one covering primary care. The role of each subgroup is to advise on the selection of new topics, to support implementation of guidelines in their topic area, and to network with others to promote guideline use.

Membership of each group is made up of members of SIGN Council (who are asked to volunteer for the group closest to their subject interest) plus one or two representatives from other organisations with a particular interest in the topic of the SSG. All groups should include a patient representative.

2.1.5 METHODOLOGY DEVELOPMENT GROUP (MDG)

The Methodology Development Group advises the SIGN Executive on the most appropriate ways of developing the SIGN guideline development methodology and provides advice and methodological support for guideline development groups. Methods of meeting these objectives include:

- Monitoring external developments in guideline development methodology, and evaluating their relevance to SIGN
- Reviewing internal developments in SIGN methodology and ensuring they are applied consistently
- Acting as an editorial board for SIGN 50
- Acting as arbitrators where guideline developers are unable to agree on the interpretation or grading of specific pieces of evidence.

All decisions or proposals from the Methodology Development Group must be ratified by SIGN Council before they are fully implemented.

Membership of the Methodology Development Group consists of:

- Quality and Information Director (Chair)
- Chair of SIGN Council (ex-officio)
- Director (ex officio)
- Three members of SIGN Council
- Programme Director
- Patient Involvement Officer
- Representation from other parts of NHS Quality Improvement Scotland
- SIGN Economics Adviser
- Up to four external (ie not directly involved in the work of SIGN) participants with knowledge or expertise in specific aspects of research methodology.

Meetings of the Committee are attended by the Executive Secretary to SIGN Council.

2.1.6 SIGN EXECUTIVE

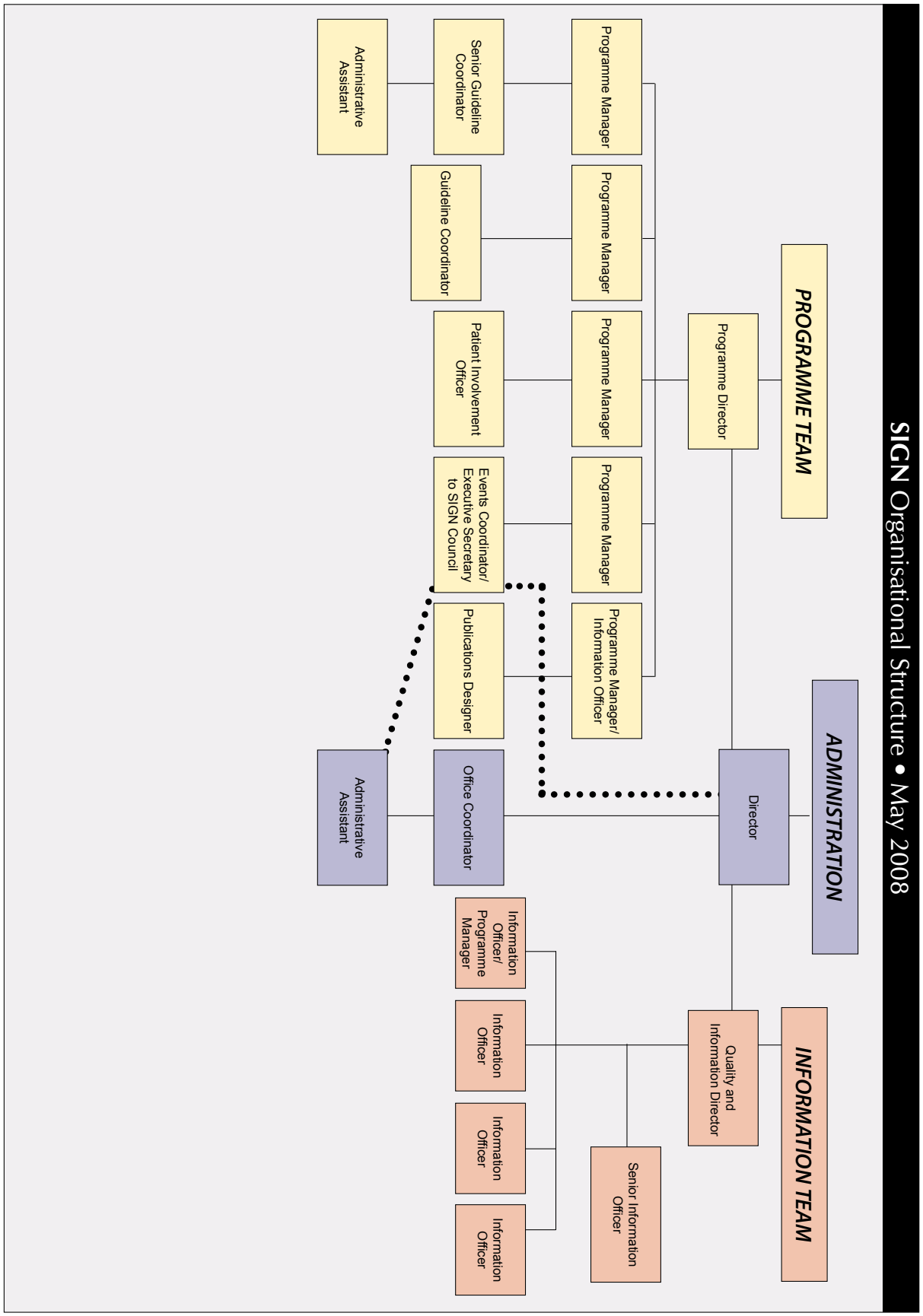
The SIGN Executive are the staff employed to run the organisation. They are responsible for the implementation of decisions taken by SIGN Council and its subgroups, and for delivering the guideline programme to time and on budget. All staff are employees of NHS Quality Improvement Scotland and as such are also required to work closely with other parts of that organisation, and to comply with their policies and procedures with the specific exception of those areas where responsibility has been retained by SIGN Council **(see Chapter 2.1.1).** A staff tree of the current SIGN staff is shown in Figure 3.

Professional healthcare qualifications are not a requirement for any SIGN staff positions, and there is an extensive mix of skills among the Executive staff, including:

- Critical appraisal (teaching and doing)
- Desk top publishing
- Editing
- Events management
- Graphics design
- Management of small group processes
- Patient involvement
- Project management
- Systematic literature searching
- Web design.

Day to day management is the responsibility of the **Senior Management Team (SMT)**. This team is made up of the three Directors, plus the Chair and Vice-Chair of SIGN Council. SMT meets regularly to resolve problems and to discuss the allocation of resources to the different parts of the guideline development programme.

Figure 3: Staff tree, SIGN Executive



2.2 FUNDING FOR GUIDELINE DEVELOPMENT

Funding from NHS Quality Improvement Scotland supports the SIGN Executive, expenses associated with individual guideline development projects (eg online search costs, library and copyright fees to obtain copies of articles for review, guideline development group meeting expenses), and the costs of printing and distributing published SIGN guidelines.

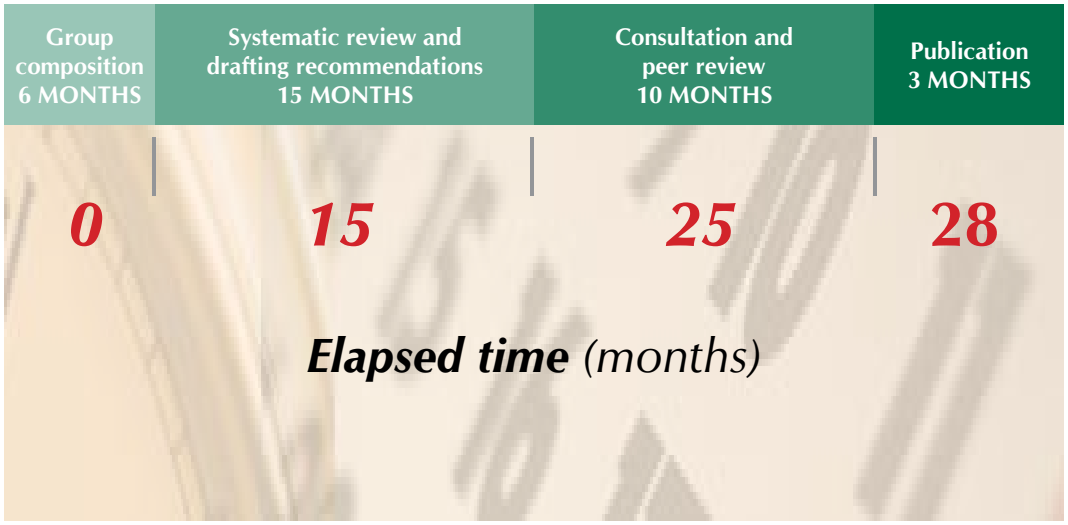
As of April 2007, the funding for SIGN was around £1 million. It is important to note that this funding does not include the majority of the professional time involved in guideline development. Members of SIGN guideline development groups do not receive any payment for their participation, although General Medical and Dental Practitioners are partially reimbursed through locum payments and travel expenses to enable them to attend guideline development group meetings. The expenses of other members of SIGN guideline development groups are met by their employing NHS Boards and universities, which make an important contribution to the SIGN initiative in this way. The expenses of any members of guideline development groups who are unable to reclaim these from their employers for any reason (eg patient representatives) are met by SIGN.

Additional sources of income for the SIGN initiative are the sale of guidelines to individuals and organisations outwith NHSScotland and a small amount made from training courses and consultancy work in the UK and overseas.

2.3 TIMESCALE FOR GUIDELINE DEVELOPMENT

The time taken to develop a SIGN guideline varies widely according to the scope of the topic under consideration, the volume of relevant literature to be critically appraised, the amount of feedback received during the consultative phases of development and, most importantly, the competing pressures on the time of members of guideline development groups. The average time taken by recent guideline development groups is illustrated in Figure 2.3 (see also Figure 9).

Figure 4: Average timescale for SIGN guideline development



2.4 INFLUENCE OF FINANCIAL AND OTHER INTERESTS

It has been recognised for some time that financial interests in, or close working relationships with pharmaceutical companies has an influence on the interpretation of evidence from clinical studies. This can affect both guideline developers and guideline users.

It is not possible to completely eliminate any possible bias from this source, nor even to quantify the degree of bias with any certainty. Despite some doubts as to how effective an answer it is, most organisations have chosen to address this problem by asking those involved in producing clinical guidelines to declare any financial or other interests related to their work on the guideline. By being explicit about the influences to which the authors are subjected, guideline producers acknowledge the risk of bias and make it possible for guideline users or reviewers to assess for themselves how likely it is that the conclusions and guideline recommendations are based on a biased interpretation of the evidence.

SIGN has taken the view that all those involved in the work of guideline development should declare all financial interests, whether direct or indirect, annually for as long as they are actively working with the organisation. An example of the form to be completed by all concerned is presented in **Annex A** to this document.

These forms are completed annually by all members of the following groups.

- SIGN Council and subgroups
- SIGN Executive
- All members of guideline development groups
- All individuals contributing peer review comments.

Signed copies are retained by the SIGN Executive and can be inspected by any interested party at the SIGN offices.

3 Selection of guideline topics

3.1 THE SIGN PROGRAMME

The experience of SIGN and other guideline developers has shown that selection of appropriate topics for guideline development is crucial. Guidelines should address a specific healthcare need and there should be an expectation that change is possible and desirable and that, if the guidelines are followed, there is potential to improve the quality of care and/or patient outcomes. There must also be robust evidence of effective practice on which to base guideline recommendations.

SIGN has limited resources for guideline development. As a result it is important to identify topics which are most amenable to guideline development. Likewise, when a published guideline is due for review it must be judged against potential new topics for inclusion in the SIGN programme.

3.2 CRITERIA FOR SELECTION OF TOPICS

Guideline topics selected for inclusion in the SIGN programme are chosen on the basis of the burden of disease, the existence of variation in practice, and the potential to improve outcome. The following criteria are considered by SIGN in selecting and prioritising topics for guideline development:

- Areas of clinical uncertainty as evidenced by wide variation in practice or outcomes.
- Conditions where effective treatment is proven and where mortality or morbidity can be reduced.
- Iatrogenic diseases or interventions carrying significant risks.
- Clinical priority areas for NHSScotland: presently these are coronary heart disease and stroke, cancer, and mental health. The strategic aims of NHSScotland are also considered. These are improving health and tackling inequalities, especially with regard to children and young people, developing primary and community care and reshaping hospital services.
- The perceived need for the guideline, as indicated by a network of relevant stakeholders.

For information on the current SIGN programme, see the SIGN website: **www.sign.ac.uk**

3.3 TOPIC SELECTION PROCESS

Any group or individual may propose a guideline topic to SIGN. In addition, the five SIGN specialty subgroups (SSGs) may suggest new topics for consideration **(see Chapter 2.1.4** for details of the SSGs).

The Chair of each SSG represents SIGN Council on the Guideline Programme Advisory Group (GPAG), which oversees development of proposals for new guidelines or for reviewing existing guidelines. This ensures that there is appropriate communication and interaction between the specialty subgroups, as most topics are relevant to more than one specialty. The Group also has representatives from other parts of NHS Quality Improvement Scotland. This should ensure that, wherever possible, SIGN's programme and the programmes of clinical standards and health technology assessments will be complementary. GPAG will also consider the work programme of other guideline developers, in particular guidelines that have been commissioned by NICE (the National Institute for Health and Clinical Excellence) in England and Wales, to avoid potential duplication of effort.

Specialty subgroups consider all new proposals, prioritise them using a suitability screening and scoring tool and submit their prioritised lists of potential guideline topics to the Guideline Programme Advisory Group. The suitability screening tool identifies the extent to which the proposal fulfils the criteria listed in **chapter 3.2**, makes an assessment of the extent of evidence on which to base the guideline and considers whether the benefits that were likely to accrue from successful implementation of the guideline recommendations would outweigh the efforts required to develop it.

GPAG will look at the combined scores from each SSG and using this information, together with the professional judgment of the group, and taking into account SIGN's work capacity, will make recommendations to SIGN Council about which proposals should be accepted onto the work programme and which should be rejected. Topics ranked highest are included in SIGN's proposed programme, depending on capacity. Proposals which are not ranked sufficiently highly to be accepted on to the programme will be reconsidered at the next topic prioritisation meeting alongside new and review topics. If the proposal still receives a low ranking on its second reading it will be returned to the SIGN specialty subgroup for reconsideration or revision.

SIGN Council dedicates one meeting each year to approving guideline topic proposals that have been recommended by GPAG as suitable candidates for the SIGN guideline development programme. Council is presented with fully worked up guideline proposals and a summary of the suitability screening results and the subsequent discussions of the Guideline Programme Advisory Group.

The final step is for the resulting topics to be forwarded to NHS Quality Improvement Scotland for approval for inclusion in the work programme before incorporation into the SIGN programme.

3.3.1 APPLICATION PROCEDURE

SIGN uses a two-stage application procedure. The initial application is made using a short, single-page application form. When a group or individual proposes a guideline topic to SIGN, their suggestion is discussed initially by the SIGN Senior Management Team (SMT). SMT use a set of defined criteria to assess whether or not the topic is an appropriate one for a SIGN guideline. If the proposed topic has the potential to meet the selection criteria the proposer is asked to complete a second, more detailed, application form.

As part of the preparatory work done before a guideline proposal is considered by the SSGs and submitted to the Guideline Programme Advisory Group, a scoping search is carried out. This is a very broad search of the literature relevant to the condition that is to be the topic of the guideline. No attempt is made to focus on specific questions at this stage. The intention is only to establish the general extent of the literature in the clinical area to see if there is likely to be sufficient good quality evidence to make an evidence based guideline feasible.

Firstly, a check is made to see if any other good quality guidelines have been produced on the subject by searching the following websites:

Guidelines International Network **(www.g-i-n.net)**

National Library for Health Guidelines finder **(www.library.nhs.uk/guidance/)**

National Guideline Clearinghouse **(www.guideline.gov)**

National Institute for Clinical Excellence **(www.nice.org.uk)**

In addition, a search for existing systematic reviews is carried out. This covers reviews produced by the Cochrane Collaboration and those covered by the databases of the Centre for Reviews and Dissemination at the University of York **(www.crd.york.ac.uk/crdweb/)**

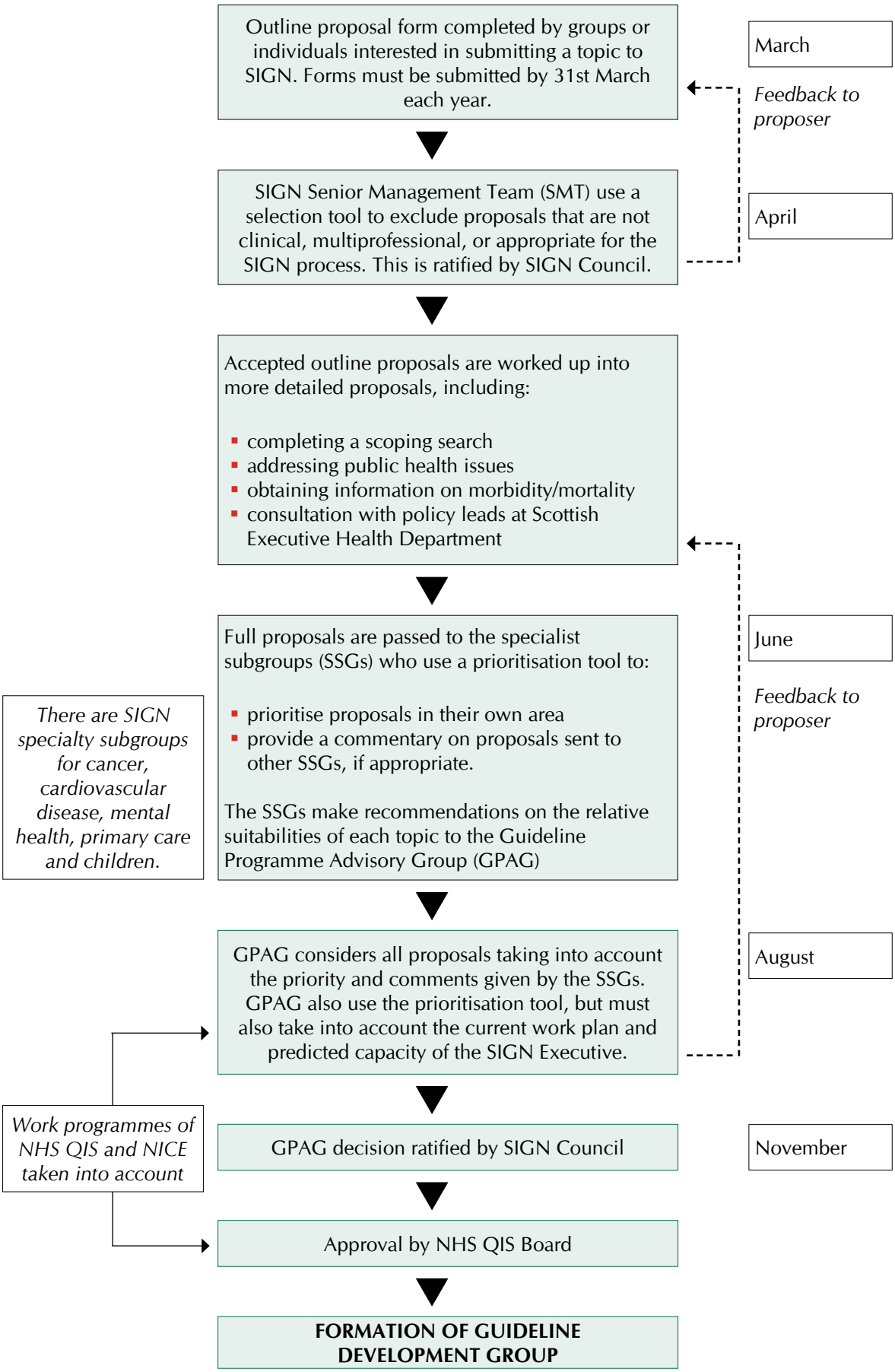
From this scoping search a report is prepared summarising the available evidence, emphasising the outcomes from systematic reviews and whether these have been positive or have identified significant work that remains to be done.

SIGN's standard guideline application form requests the following information:

1. A summary of the clinical problems and outcomes to be addressed.
2. Details of the group(s) or institution(s) supporting the proposal.
3. A brief background to the clinical topic which will be addressed by the proposed guideline.
4. Evidence of variation in practice in the management of the condition.
5. An indication of the benefits likely to arise from the development and successful implementation of the guideline.
6. A definition of the patient group to which the guideline will apply. This should include consideration of whether any specific social groups or minorities are likely to be particularly affected, either favourably or adversely, by changes in healthcare provision in the topic area under consideration.
7. A definition of the aspects of management of the clinical condition which the proposed guideline will address and an indication as to whether the guideline will apply to primary or secondary care, or both.
8. An indication of the healthcare professionals potentially involved in developing the guideline.
9. An indication of the size and strength of the evidence base which is available to support recommendations on effective practice, citing key supporting papers.
10. Details of any existing guidelines or systematic reviews in the field.

The procedure for selection of new topics for SIGN guidelines is illustrated in Figure 3.1. The application form to request consideration by SIGN of a specific guideline topic and the full guideline proposal form are available from the SIGN Executive or can be downloaded from the SIGN website: **www.sign.ac.uk**

*Figure 5: S*election of new topics for SIGN guideline development



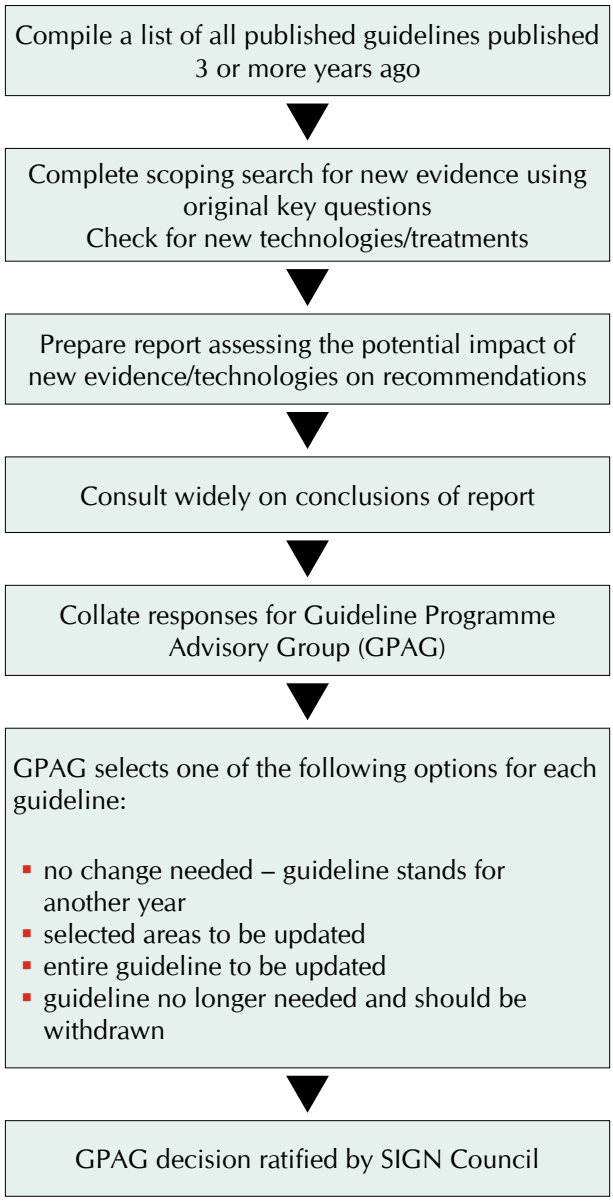
3.4 UPDATING PUBLISHED GUIDELINES

3.4.1 SCHEDULED UPDATES

SIGN has made a commitment to consider whether or not published guidelines need to be reviewed after a period of three years and all SIGN guidelines carry a statement indicating that they will be considered for review three years after publication. A full review of a guideline after a fixed time period is not always appropriate as new evidence is published at different rates in different fields. It also imposes a workload for future years that may not be achievable in practice. A further factor that will influence the decision on whether and how to review a guideline is the emergence of any evidence of inequality in access to services between different social groups that can be addressed through guideline recommendations.

3.4.2 UPDATE PROPOSALS

Figure 6: Selection of guidelines for updating



When a guideline is considered for updating, there are four possible outcomes:

- the guideline, as it stands, will be revalidated for a further year
- the guideline will undergo a complete review
- the guideline will undergo a partial or selective review
- the guideline will be withdrawn.

A fifth option, which is likely to be applicable in only a small number of cases, is to make the guideline into a 'living guideline'. This option involves keeping the evidence under constant review and updating the guideline on a regular basis. A three year trial project using this process for the asthma guideline (produced in conjunction with the British Thoracic Society) is nearing completion, and evaluation of this project will influence the extent of future use of this approach to guideline updating.

As a first step, an update search is carried out looking for evidence based guidelines, HTAs, and systematic reviews produced since publication of the last version of a guideline. These searches are based on the key questions and search strategies used in the original guideline.

Results are presented in the form of summaries of the findings of the papers that have been identified.

These searches include an element of horizon scanning to see if there are new treatments or technologies that should be considered as part of the update.

The search results are incorporated into a report that summarises the new evidence and looks at how it will impact on the recommendations made in the existing guideline. This report will also note any new areas or key questions that have emerged since the previous publication.

The review report is then widely circulated for comment within NHSScotland, to Royal Colleges and other professional bodies (through their representatives on SIGN Council), to relevant patient organisations, and to other organisations providing guidance or advice to the NHS in any part of the UK. Responses to this consultation are gathered and presented to the Guideline Programme Advisory Group. On the basis of these reports combined with input from their professional networks GPAG then makes recommendations to SIGN Council on which guidelines should be updated, and whether a full or selective update is appropriate.

At their November meeting, SIGN Council will agree which guidelines are to be updated and prioritise the updates along with new guideline proposals for addition to the SIGN guideline programme.

Information on the status of guidelines due for updating, or currently being updated, is provided on the SIGN website: **www.sign.ac.uk**

3.4.3 SELECTIVE UPDATE PROCEDURE

When a guideline has been accepted for a selective update, the process for carrying out the update will be largely the same as that described elsewhere in this manual. The principal difference is that the update will focus on those chapters of the original guideline that have been identified as being in need of updating. The same methodological principles apply, though the nature of the chapters being reviewed may necessitate a slightly different composition from the original guideline group. If a chapter on surgical interventions is a major part of an update, for example, the guideline group is likely to include more surgeons and theatre staff than (say) pharmacists or home care workers.

The process begins with a review of the patient literature. This will feed into a review of patient issues **(see Chapter 4)** that seeks to establish whether any new issues have emerged since the last version of the guideline.

Unlike new topics, where the main literature searches do not get underway until the key questions have been established by the guideline group, literature searches for systematic reviews and randomised controlled trials are started while the guideline group is being assembled. These searches are based on the recommendations in the chapters of the guideline that have been identified as being in need of updating. They seek to update and build on the evidence base used in the original guideline. The only new questions that may be addressed are any arising from the patient issues search, or that arose from new developments identified during the process of authorising the update.

Once searches are completed, the Information Officer working with the guideline group will carry out a preliminary sift to remove irrelevant material. The Chair or a designated alternative from the new guideline group will carry out a second sift to remove any further papers seen as clinically irrelevant or inappropriate. The remaining papers will be obtained for review and shared among guideline group members for critical appraisal. The Information Officer will extract relevant data from those papers deemed acceptable by the group, and produce evidence tables.

From this point the processes used will be the same as those used for a new guideline. A possible exception is the need for a national meeting. Here the guideline group may decide whether or not the proposed changes are sufficiently far reaching as to justify such wide consultation. If a national meeting is not held, the first draft of the guideline is published on the SIGN website for a fixed period, during which time potentially interested parties will be alerted to its presence and invited to submit comments.

3.4.4 WITHDRAWING GUIDELINES

From time to time it is necessary to consider withdrawing guidelines which are outdated or no longer relevant. Proposals to withdraw guidelines are submitted initially to the Guideline Programme Advisory Group and if it agrees with the proposal it is submitted to SIGN Council for final approval.

Once it has been agreed to withdraw a guideline, all versions of the text and any associated material will be removed from the SIGN website. The list of published guidelines will be amended to show the guideline as withdrawn, with a note of the reason for withdrawal and reference to any alternative sources of advice.

Guidelines may be withdrawn for any of the following reasons.

- Superceded by a more recent or more comprehensive guideline
- Evidence that the guideline is fully complied with by NHSScotland, and has become accepted practice
- Emergence of new treatments or preventive measures that render the guideline irrelevant.

3.4.5 MONITORING AND INTERIM UPDATES

All comments received on published SIGN guidelines, or information on important new evidence in the field, or evidence of impacts on equality groups are fed back to the guideline development group, either for immediate response or for more detailed consideration on review of the guideline. Any updates to the guideline which might be required in the interim period prior to review are noted on the SIGN website.

4 Involving patients and their representatives

4.1 PATIENT INVOLVEMENT IN GUIDELINE DEVELOPMENT

The term *patients* is used throughout this chapter as a generic term to describe patients, carers, lay representatives and those who represent and/or support patients in the voluntary sector.

Patient involvement is 'the appropriate, active participation of patients, carers and patient representatives as partners in their own care and in the planning, monitoring and development of health services.[8] The potential contribution of patient representatives has been recognised for some time, as well as the difficulties in making that contribution effective.[9]

Patients may have different perspectives on healthcare processes, priorities, and outcomes from those of health professionals. The involvement of patients in guideline development is therefore important to ensure that guidelines reflect their needs and concerns. The purpose of patient involvement is to ensure that the guideline addresses issues that matter to them and that their perspectives are reflected in the guideline. Patients can identify issues that may be overlooked by health professionals, can highlight areas where the patient's perspective differs from the views of health professionals, and can ensure that the guideline addresses key issues of concern to patients.

Patient representatives on guideline development groups can remind the other group members of the limitations of the scientific findings in respect of age, disability,, gender, ethnicity, race, sexual orientation, quality of life and life circumstances such as accessibility. They help to ensure that the group gives consideration to the specific needs of particular ethnic or social groups - information and communication needs, for example. Factors such as age and gender may have an influence over choice of treatment setting – eg males may be less likely to access GP services - and patient representatives can remind the group of this.

A wide range of other issues can be drawn out by patient representatives to make sure a guideline addresses the needs of all those affected by a condition. The influence of religion/belief on compliance with treatment -. eg complying with a recommended diet or medication, or a different approach to STI screening being required for people in prison and those who are homeless.

Patient representatives can also assist the group on the use of clear and sensitive language in the guideline.

4.2 IDENTIFYING PATIENTS' VIEWS

4.2.1 LITERATURE SEARCH

SIGN has developed a literature search strategy to identify both qualitative and quantitative studies that reflect patients' experiences and preferences in relation to the clinical topic **(see Chapter 6.1).** This search is performed at least three months prior to the first group meeting to ensure adequate time to obtain relevant papers and summarise their findings for presentation at the first guideline group meeting.

The types of studies identified generally include patients' views on:

- positive and negative experiences of the condition, including diagnosis, medication and other treatments, follow-up care and quality of life
- unfulfilled needs
- information needs and preferences
- participation in decision making about treatment
- overall satisfaction with care received.
- A copy of the Medline version of the patient search strategy is available on the SIGN website **www.sign.ac.uk**

4.2.2 PATIENT ORGANISATIONS AND SIGN PATIENT NETWORK

SIGN writes to the organisations and charities that aim to represent and/or lobby for patients at least four months before the first meeting of the guideline development group, asking them to inform SIGN of the issues they think the guideline should address. A form is supplied to enable them to structure their feedback in a useful way and, importantly, to indicate the source(s) of their suggestions (eg telephone help line data, surveys).

SIGN also writes to members of the Patient Network asking them which issues they think the guideline should address. The Patient Network is a database of patient, carer and other user representatives. The Network includes contacts for both individuals and organisations, including NHS Board Designated Directors for patient and public involvement, equality and diversity group stakeholders (for example,eg REACH community health project), previous and current patient representatives on SIGN guideline development groups, representatives from patient advocacy services, representatives from patient support organisations, and representatives from relevant Scotland wide groups.

4.2.3 OTHER NHS ORGANISATIONS

SIGN writes to various other NHS organisations at least four months before the first meeting of the guideline development group to find out if any local research on patient views has been performed. This might include, for example, patient focus groups to help in the redesign of services, or questionnaire studies to gauge levels of patient satisfaction with existing services. Reports such as this tend not to be published even though they are in the public domain and can be very useful as a snap shot into current patient issues and concerns regarding particular NHS services and treatments.

4.2.4 DIRECT FEEDBACK FROM USERS OF THE SERVICE

Where published evidence is scarce and inadequate feedback from patient organisations has been received, patient and carer views may be sought via direct contact with users of the service. Techniques employed to date have included focus groups with patients in different regions of Scotland, attending patient support group meetings, and SIGN organised meetings for patients and carers. All of these approaches have provided valuable information that has been fed back directly to guideline groups to influence the remit and key questions underpinning the guideline. Often the guideline development group identifies a need for further input from patients and carers at a later stage of the guideline development process. Focus groups can be carried out and the findings used to complement the scientific evidence.

Running focus groups requires expert facilitation. Views are sought from both men and women of different age groups, in both rural and urban communities. Special efforts are made to include those who are socially excluded and may be less likely to join a local or national organisation. SIGN does this by working with healthcare professionals, local community groups and schools who can help identify people to take part.

4.2.5 PRESENTING THE FINDINGS

The Patient Involvement Officer reviews the results of the patient literature search, and seeks to identify common themes that emerge from the literature. These themes are then integrated with the issues that emerge from the other approaches described above presented at the first meeting of the guideline development group by the Patient Involvement Officer.

The group is asked to take cognisance of these issues when it drafts its key questions. Once a first draft of the key questions has been prepared, the Information Officer working with the group along with the Patient Involvement Officer compares the questions with the issues highlighted through the consultative process and highlights any that have not been included in the key questions. At a subsequent group meeting the results of this comparison are presented to the group, and they are asked to consider whether the questions should be revised.

Guideline groups are not obliged to take on board all the issues raised through the patient consultative process, but they are expected to give explicit reasons if they choose to omit particular topics that have arisen from this source.

4.3 RECRUITMENT OF PATIENTS TO GUIDELINE DEVELOPMENT GROUPS

SIGN recruits a minimum of two patient representatives to guideline development groups by inviting nominations from the relevant "umbrella", national and/or local patient focused organisations in Scotland. Where organisations are unable to nominate, patient representatives are sought via other means, eg from consultation with health board public involvement staff. Where patients have been consulted directly (eg if a focus group has been held) this may also provide a source of possible future patient and carer representatives.

Details of the role of the patient representatives, the support they will be given, the commitment required and useful attributes for representatives are provided to allow informed nominations to be made.

4.4 ROLE OF PATIENT REPRESENTATIVES ON GUIDELINE DEVELOPMENT GROUPS

Although their areas of expertise will vary, members of the guideline development group have equal status on the group. A key role for patient and carer representatives is to ensure that patient views and experiences inform the group's work. This includes:

- ensuring that key questions are informed by issues that matter to patients
- identifying outcome measures they think are important for each key question
- considering the extent to which the evidence presented by group members has measured and taken into account these outcome measures
- identifying areas where patients' preferences and choices may need to be acknowledged n the guideline
- making sure that the degree to which the evidence addresses patients' concerns is reflected in the guideline
- helping to write the Information to Patients chapter of the guideline, including identifying sources of further information
- raising awareness of patient issues at the National Open Meeting by preparing a presentation ssisting SIGN with the identification of voluntary organisations and charities to invite to the National Open Meeting
- helping to ensure that the guideline is sensitively worded (for example treating patients as people and not as objects of tests or treatments)
- identifying individuals to take part in the peer review process
- assisting SIGN with the collection of patient views eg by helping to prepare questions for focus groups
- helping SIGN with consultation arrangements
- appraising literature (if the individual chooses to do so)
- raising awareness of the SIGN guideline among members of their support group and members of the public.

No formal qualifications are needed but it may be helpful if patient representatives have some of the following:

- experience of the guideline condition (eg as someone who has, or has had the condition, or a carer or relation of someone who has or has had the condition)
- an understanding of the experiences and needs of a wider network of patients (eg as a member of a patient support group)
- time to commit to the work of the group (eg attending meetings, background reading, commenting on drafts)
- some familiarity with medical and research language (although members of the guideline group should help with specific technical terms)
- willingness to feed in the views of patient/carer groups not represented on the guideline group
- ability to be objective
- good communication and team working skills.

4.5 SUPPORT FOR PATIENT REPRESENTATIVES ON GUIDELINE DEVELOPMENT GROUPS

SIGN supports patient representatives by:

- delivering introduction to SIGN training for patient representatives
- offering telephone and email support
- inviting new patient representatives to join the SIGN Patient Network
- providing clear guidance on their roles and responsibilities within the group
- ensuring opportunities to attend training events are open to all guideline development group members
- inviting patient representatives to informal events.

In addition, SIGN is exploring the development of other types of support for patient representatives including the production of a patient handbook and CD-ROM, introducing a "buddy" system, and the development of a critical appraisal course aimed specifically at lay representatives.

The Chair of each guideline development group is asked to support patient representatives by:

- ensuring patient representatives are fully engaged with the group
- addressing the group if contributions by patient representatives are not acknowledged appropriately
- welcoming and encouraging contributions from patient representatives.

4.6 WIDER CONSULTATION WITH PATIENTS AND CARERS

Further patient and public participation in guideline development is achieved by involving patients, carers and voluntary organisation representatives at the National Open Meeting which is held to discuss each draft guideline **(see Chapter 8.1).** The meetings are advertised widely and are free of charge.

Patient representatives are invited to take part in the peer review stage of each guideline and specific guidance for lay reviewers has been produced.

Members of the SIGN patient network are also invited to comment on draft documents such as patient versions of guidelines, patient chapters of guidelines and other literature aimed at patients.

5 The guideline development group

5.1 COMPOSITION OF THE GUIDELINE DEVELOPMENT GROUP

One of the US Institute of Medicine's strongest recommendations for 'good guidelines' was that the process of developing guidelines should include participation by representatives of key groups and disciplines affected.[3] Farmer has also stressed that guidelines should not be developed by academics and senior clinicians insulated from the day to day pressures involved in providing medical care, warning that "Unless a guideline accurately reflects the routine working practices of most doctors it will act only as a gold standard to be admired."[10]

A Canadian Medical Association workshop held in 1992 to establish the principles on which to base the formulation of individual clinical practice guidelines also recommended that clinical practice guidelines should be developed by physicians in collaboration with representatives of those who will be affected by the specific intervention(s) in question, including relevant physician groups, patients, and other health care providers as appropriate.[11] Studies have shown that the balance of disciplines within a guideline development group has considerable influence on the guideline recommendations.[12, 13] Establishing a multidisciplinary guideline development group is therefore important to ensure that:

- all relevant groups are represented, providing expertise from all stages in the patient's journey of care
- all relevant scientific evidence will be located and critically evaluated
- practical problems with using the guideline will be identified and addressed
- stakeholder groups will see the guideline as credible and will cooperate in implementation.[14,15]

Following the acceptance of a guideline proposal into the SIGN development programme **(see Chapter 3)**, the SIGN Executive discusses which specialties and professions should be represented on the guideline development group with the topic proposer(s), with advice from the appropriate Specialty Subgroup(s) and SIGN Council. This ensures that all of the relevant professions in Scotland can input into and feel ownership over the guideline development process.

SIGN guideline development groups vary in size depending on the scope of the topic under consideration, but generally comprise between 15 and 25 members. There is necessarily a trade-off between the number of organisations or specialties that should be represented on the guideline development group, and achieving the optimum group size for effective decision making. Care is also taken to ensure that the group is balanced geographically, with representatives from across Scotland.

In putting together a guideline development group, SIGN is aware of the many psychosocial factors, including the problems of overcoming professional hierarchies that can affect small group processes. Grimshaw (1995) states: "To ensure that guidelines achieve their full potential… requires a programme of research and development that accords at least as much thought to the psychology of group dynamics as the science of systematic reviews".[15] Research into the progress and functioning of SIGN's own guideline development groups has shown the impact of professional or status differences on members' contributions to group discussions.[16,17] A clear relationship between the perceived status of a group member and their level of contribution to group discussions was identified. This may be difficult to avoid, as members with highest status often have the greatest amount of research expertise, which is of great benefit when interpreting evidence. Care is therefore taken to offer support to those who may feel at an initial disadvantage compared with the group's "experts" **(see Chapter 5.2).** This begins with selecting a balanced group that is not "top heavy" and a chairperson with an awareness of these hierarchies and with skills in facilitating full participation by all group members.

The process for establishing SIGN guideline development groups is illustrated in Figure 7. The membership of a typical guideline development group is shown in Figure 8.

Figure 7: Establishing the guideline development group

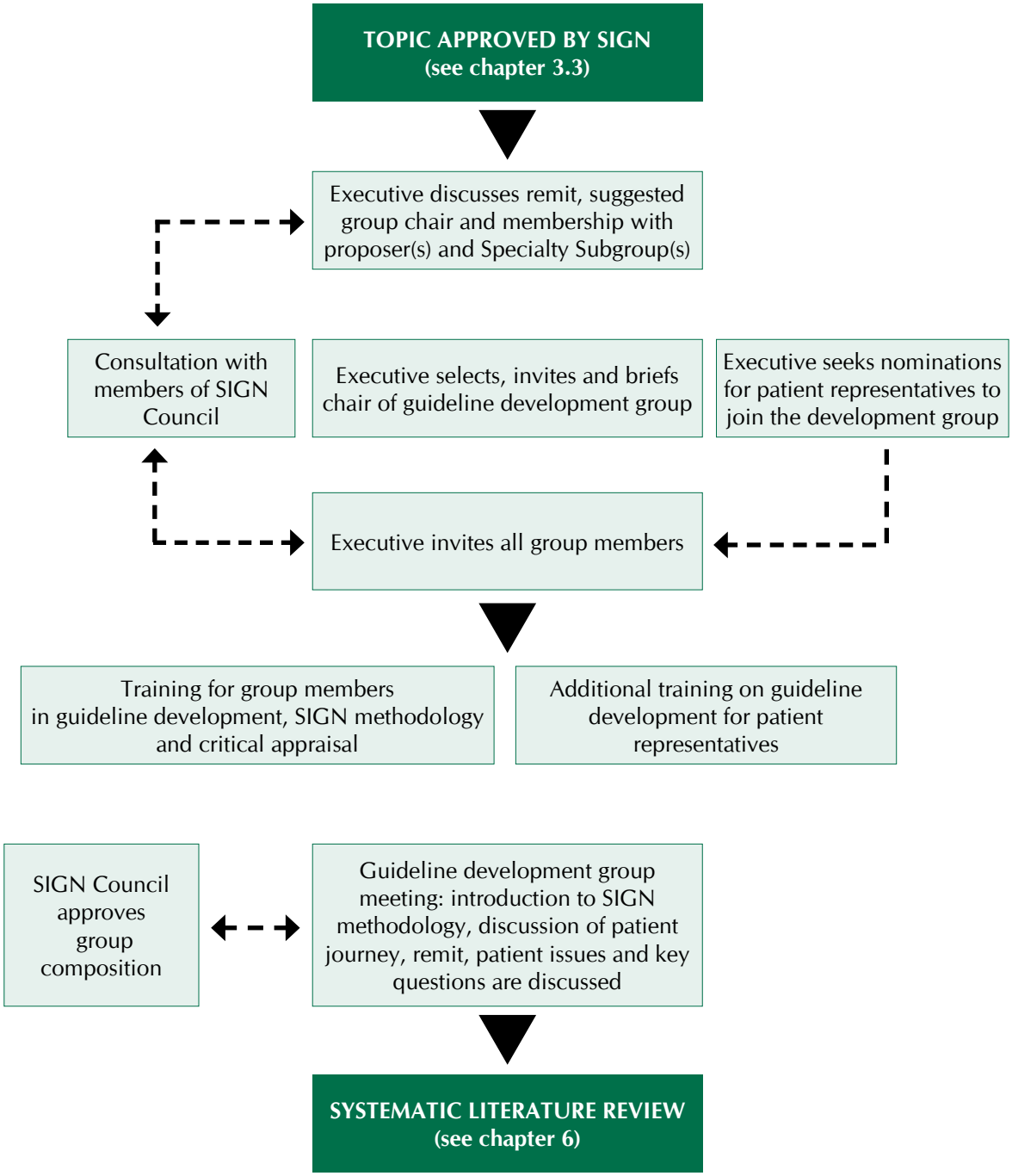


Figure 8: Membership of the SIGN peripheral arterial disease guideline development group

Chairman: Professor of Epidemiology, Public Health Sciences, Edinburgh

Group members:

Consultant Vascular Surgeon, Aberdeen

Consultant Vascular Surgeon, Dunfermline

General Practitioner, Beith

Health Economist, Glasgow

Clinical Nurse Specialist, Edinburgh

Vascular Liaison Nurse, Glasgow

Vascular Liaison Nurse, Inverness

Vascular Nurse, Stirling

Patient representative, Glasgow

Patient representative, Penicuik

Chief Pharmacist, Dundee

Senior Vascular Physiotherapist, Inverness

Superintendent Physiotherapist, Glasgow

Professor of Vascular Medicine, Dundee

Public Health Lecturer, Edinburgh

Specialist Registrar in Public Health, Edinburgh

Vascular Radiologist, Edinburgh

Vascular Technologist, Glasgow

SIGN Programme Manager

SIGN Information Officer

5.2 RESPONSIBILITIES OF DEVELOPMENT GROUP MEMBERS

SIGN's experience in coordinating the work of over 100 guideline development groups has shown that the role of the group leader is crucial to ensure that the group functions effectively and achieves its aims.[18] Chairs of guideline development groups must be sensitive to pre-existing inter-professional tensions and hierarchies and ensure that all members of the group feel able to contribute fully to the guideline development process.

The most successful guideline development groups have a Chair who is aware of and constantly attentive to small group processes (eg how the group interacts and communicates, decision making processes and chairing strategies). The Chair must be prepared to overcome potentially serious difficulties by careful negotiation.[16,17]

The SIGN Programme Manager assigned to each guideline helps the Chair to identify potential barriers to successful group work, to plan and progress the guideline development project, and acts as facilitator at group meetings. Some SIGN guideline development groups are co-chaired by the SIGN Programme Manager and the group leader in order to help reduce potential conflicts.

Guideline development group members in turn must make a full commitment to the group and the tasks involved in guideline development, and be responsible for indicating areas of concern to the Chair. Guideline development group members should also bear in mind that they represent both a geographical region and a specialty or professional group, and must be prepared to consult with colleagues to ensure that the widest possible range of views are considered.

Each guideline development group requires a mix of the following skills:

- clinical expertise (eg medical, surgical, nursing etc.)
- other specialist expertise (eg health economics, social services)
- practical understanding of problems faced in the delivery of care
- communication and team working skills
- critical appraisal skills.

A healthcare professional joining a guideline development group is not expected to be an expert in all of these areas. Many group members may feel they have only one or two of these skills, but at some point in the development of the guideline, their knowledge and experience will be invaluable.

Many potential development group members are concerned that their critical appraisal skills may not be sufficient to complete the systematic review of the literature. To address this, SIGN runs a range of training seminars in critical appraisal skills that all group members are encouraged to attend. In addition, guideline development groups are also supported throughout the development process by the SIGN Executive. The Programme Manager and Information Officer assigned to each guideline development group give regular presentations on SIGN methodology, and will also ensure that methodological checks are correctly applied and that the development process itself is fully documented.

The life span of each guideline development group is approximately 28 months, with groups meeting on average once every two months, although groups may form subgroups which meet more frequently. The development timetable of a typical guideline, and the associated tasks, is shown in figure 9. Guideline development groups are supported by the SIGN Executive.

The work commitment of the healthcare professionals and patients who take part in the development of a SIGN guideline is significant and should be recognised before accepting an invitation to join such a group. In addition to taking on the responsibility of representing both a geographical region and a specialty group, group members need to pledge a considerable amount of their time to guideline development. Prospective guideline development group members are encouraged to attend critical appraisal training prior to joining a group to ensure that they understand the commitment they are about to undertake.

Figure 9: Timetable for guideline development

Months 1-3	▪ Define remit of guideline ▪ Attend critical appraisal training ▪ Plan development process ▪ Share relevant knowledge and experience ▪ Identify key questions/terms for literature search (with advice from SIGN Information Officer ▪ Discuss requirements of systematic literature review	***Prepare group and finalise remit:*** **3 months**
Months 1-10	▪ Review abstracts to select papers for detailed review ▪ Clarify criteria used to select or reject papers ▪ Detailed literature review, grading and synthesis of evidence (often undertaken in subgroups)	***Literature search and appraisal: 10 months***
Months 11-15	▪ Draft recommendations derived from evidence review ▪ Draft guideline prepared ▪ National open meeting held to present and discuss draft recommendation	***Draft guideline: 5 months***
Months 16-25	▪ Feedback from national meeting incorporated into draft guideline. Draft is edited by group with assistance from SIGN Executive ▪ Guideline sent for external peer review ▪ Feedback from external reviewers incorporated into draft guideline	***Post national meeting review; Peer review 10 months***
Months 26-28	▪ Review by SIGN Editorial Group ▪ Publication and dissemination	***Final editing***

6 Systematic literature review

Guidelines based on a consensus of expert opinion or on unsystematic literature surveys have been criticised as not reflecting current medical knowledge and being liable to bias.[19,20] SIGN guidelines are therefore based on a systematic review of the evidence. Systematic review is defined as "an efficient scientific technique to identify and summarise evidence on the effectiveness of interventions and to allow the generalisability and consistency of research findings to be assessed and data inconsistencies to be explored".[21]

The SIGN approach leads to guidelines that are essentially the direct product of the systematic review. There is no separate report of the review or its conclusions, though all the stages of the review process are thoroughly documented (see below). Because the reviews are largely undertaken by members of SIGN guideline development groups working part time on the project, and within a limited timescale, their coverage of the literature may be more limited than those carried out by dedicated systematic review groups such as the Cochrane Collaboration. Nevertheless, the essential elements of systematic review are met:

- the literature is identified according to an explicit search strategy
- selected according to defined inclusion and exclusion criteria
- evaluated against consistent methodological standards.

The benefits of the SIGN approach derive from the close involvement of guideline developers with the synthesis of the evidence base, allowing them to apply their *considered judgement* when deriving recommendations **(see Chapter 7)**, and from encouraging a sense of ownership of the guideline amongst all those involved in the process.

6.1 ADDRESSING PATIENT ISSUES IN THE LITERATURE SEARCH

Incorporating the patient's perspective from the beginning of the development process is essential if it is to influence the coverage of the final guideline. One of the measures used to achieve this is to conduct a specific search on patient issues in advance of the first meeting of the guideline development group.

This search is designed to cover both quantitative and qualitative evidence, and is not limited to specific study designs. It is carried out over the same range of databases and sources as the main literature review, but will normally include both nursing and psychological literature even where these are not seen as particularly relevant to the later searches of the medical literature.

The use of this literature search is discussed in more detail in **Chapter 4.2**

6.2 USING EXISTING GUIDELINES

The guidelines identified in the scoping search carried out for the original guideline proposal **(see Chapter 3.4)** will be presented to an early meeting of the guideline development group to allow it to consider what has been done already.

In some cases good quality, directly relevant guidelines will have been produced on some of the issues that fall within the remit of the new guideline. In these circumstances reference will be made to the existing guidelines rather than repeating work that has already been completed. All guidelines must be evaluated using the AGREE instrument and be shown to have followed an acceptable methodology before they can be considered for use in this way.

In other cases existing guidelines may not be directly relevant to NHSScotland, or may be found to have methodological weaknesses. If these guidelines are based on a well conducted systematic review, the guideline group may be able to use the evidence base from those guidelines as a starting point for its own review.

As more good quality guidelines are being produced by other agencies, SIGN is considering use of the ADAPTE instrument [22,23] to adapt guidelines produced elsewhere for use in NHSScotland. A trial of this process started in April 2007, looking at the guideline on obesity produced by the National Institute for Health and Clinical Excellence.

6.3 DEFINING KEY QUESTIONS

The training in critical appraisal and guideline development offered to members of SIGN guideline development groups encourages them to break down the guideline remit into a series of structured key questions using the PICO format:

Patients or population to which the question applies

Intervention (or diagnostic test, exposure, risk factor, etc.) being considered in relation to these patients

Comparison(s) to be made between those receiving the intervention and another group who do not receive the intervention

Outcome(s) to be used to establish the size of any effect caused by the intervention.

The **Patients** or **population** to be covered by the literature searches is largely defined by the presence of the particular condition that the guideline will cover. It should be made clear at this stage, however, which age groups are to be covered. For searching the main medical databases these can be split into:

- Neonates < 1 month
- Infants up to 2 years
- Pre-school children aged 3-5 years
- Children aged 6-12
- Adolescents 13-18 years
- Adults 19-45 years
- Middle aged 46-64
- Aged 65-79 years
- Elderly 80 + years

Consideration should also be given as to whether any particular ethnic or social groups have particular needs in relation to the topic under review. If it is thought that any group needs particular consideration in relation to a key question (people of African origin who have sickle cell disease, for example, may need a different approach to antibiotic treatment) the needs of these groups should be specifically addressed in the key questions and subsequent literature searches.

It is worth emphasising here that questions should be addressed even if it is not thought there will be any good evidence. If there is in fact no good evidence, then highlighting it as an area for research is a useful outcome in itself.

Exclusion of any group from the population covered by the guideline should be identified when setting the key questions, and reasons given for their exclusion.

The **Interventions** (which in this context includes diagnostic tests, risk factors, risk exposure) must be specified clearly and precisely. The only exception is in drug therapy where drug classes should be used in preference to specific agents unless there is a clear reason for focusing on a named agent.

The decision on **Comparisons** is mostly between placebo / no treatment, or comparison with alternative therapies. It should be borne in mind that where there is an existing treatment comparisons with placebo or no treatment are not ethically acceptable.

It is important to specify **Outcomes** in advance, and to think of these in terms of what outcomes will influence the views of guideline group members as to how effective a particular intervention is. For some questions there will be a wide range of outcomes used in the literature, and if useful comparisons are to be made across studies it must be made clear which of these outcomes are important.

As far as possible outcomes should be objective and directly related to patient outcomes (eg length of time to next cardiovascular incident or survival time, rather than just reductions in blood pressure). It is also important to include outcomes that are important to patients, rather than focusing entirely oin clinical outcomes.

These questions then form the basis of the literature search, which is undertaken by a SIGN Information Officer.

Definition of a set of clear and focused clinical questions is fundamental to the successful completion of a guideline development project. It is also important to be realistic about the number of questions that can be addressed in a single guideline if the final product is not to be too large to be useable. A large number of key questions also implies a very high workload for the developers, and care must be taken to ensure this is kept within manageable limits. Where the number of questions reaches 40 or more, serious consideration must be given as to whether the scope of the guideline needs to be redefined.

Deciding the key questions is entirely the responsibility of the guideline development group who must apply its knowledge and experience to ensuring the questions address the key issues in the area to be covered by the guideline. The Information Officer working with the group will provide guidance on the formatting of the questions, and ensure they are in a format likely to produce useable results. They will also ensure that the key questions address most, if not all, the issues identified through the patient consultation exercise **(see Chapter 4.2).**

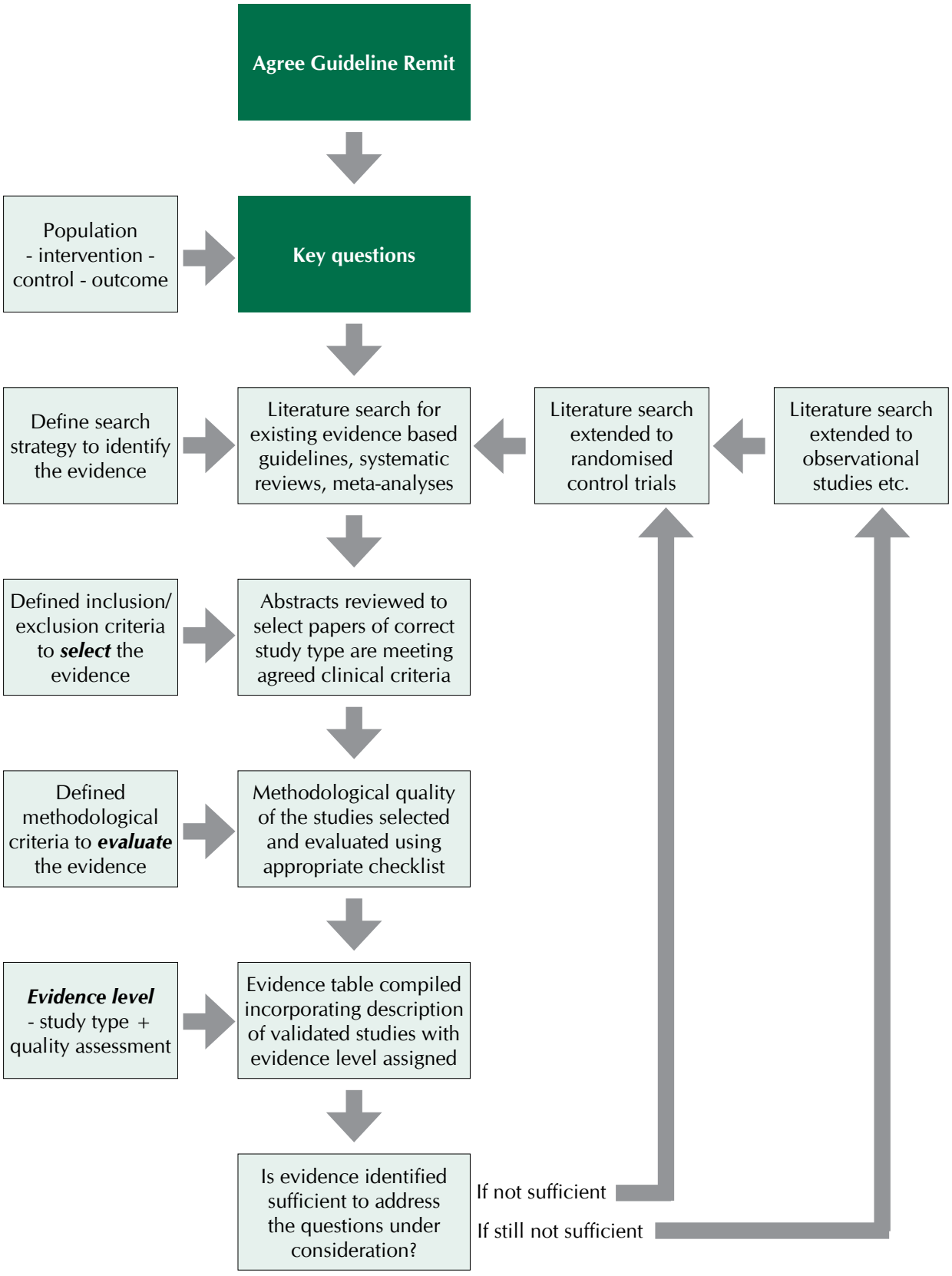
6.4 IDENTIFYING AND SELECTING THE EVIDENCE

The literature search must focus on the best available evidence to address each key question, and should ensure maximum coverage of studies at the top of the hierarchy of study types **(see Annex B).** SIGN uses a set of standard search filters that identify:

- Systematic reviews.
- Randomised controlled trials.
- Observational studies
- Diagnostic studies
- Economic studies.

These search filters are available from the SIGN website. The systematic literature review procedure is illustrated in Figure 10.

Figure 10: Systematic literature review



In order to minimise bias and to ensure adequate coverage of the relevant literature, the literature search must cover a range of sources. As a minimum, SIGN requires searches to cover the Cochrane Library, Embase, Medline, NHS Economic Evaluations Database (NEED) and the Internet. It is expected that in most cases the search will also cover additional sources specific to the topic under review.

The period that the search should cover will depend on the nature of the clinical topic under consideration, and will be discussed with the guideline development group. For a rapidly developing field a 5 or 10-year limit to the search may be appropriate, whereas in other areas a much longer time frame might be necessary.

All the main search strategies are subject to an independent review by an Information Scientist based elsewhere in NHS Quality Improvement Scotland.

SIGN does not undertake hand searching of key journals as part of the literature review. It is accepted that this means some relevant trials may be missed, and introduces the possibility of a degree of bias in the process. However, given time and resource constraints, it is not feasible for this to form part of the process.

A listing of the Medline search strategies used for the guideline, plus notes of any significant variation on other databases, is published on the SIGN website at the time of the National Meeting associated with the guideline. This strategy will remain on the wWebsite as part of the supporting material for the guideline when it is published.

Before any papers are acquired for evaluation, sifting of the search output is carried out to eliminate irrelevant material. A preliminary sift of each search result is carried out by staff at the SIGN Executive, normally by the individual that carried out the search. Papers that are clearly not relevant to the key questions are eliminated. Abstracts of remaining papers are then examined and any that are clearly not appropriate study designs, or that fail to meet specific methodological criteria, will also be eliminated at this stage.

A final sift is carried out by one or two individuals from the guideline development group, who will reject other papers that do not meet specific clinical or other exclusion criteria that have been agreed by the development group. Only when all stages of search result sifting have been completed will the remaining papers be acquired for evaluation.

All sifting is carried out according to an agreed protocol setting out the criteria used to select papers for inclusion or elimination from the process.

In practice, a single search does not cover all the questions being addressed within a guideline. Different questions may be best answered by different databases, or may rely on different levels of evidence. Information Officers take an iterative approach to the task, carrying out a search for high level evidence in the first instance. After the results of this search have been evaluated, the questions may be redefined and subsequent searches focused on the most appropriate sources and study types. This iterative process is illustrated in Figure 10.

6.5 EVALUATING THE EVIDENCE

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. The result of this assessment will affect the **level of evidence** allocated to the paper, which will in turn influence the **grade of recommendation** that it supports **(see Chapter 7).**

The methodological assessment is based on a number of key questions that focus on those aspects of the study design that research has shown to have a significant influence on the validity of the results reported and conclusions drawn. These key questions differ between study types, and a range of checklists is used to bring a degree of consistency to the assessment process. SIGN has based its assessments on the MERGE (Method for Evaluating Research and Guideline Evidence) checklists developed by the New South Wales Department of Health,[24] which have been subjected to wide consultation and evaluation. These checklists were subjected to detailed evaluation and adaptation to meet SIGN's requirements for a balance between methodological rigour and practicality of use. Copies of these checklists and accompanying notes on their use are included in **Annex C.**

The assessment process inevitably involves a degree of subjective judgement. The extent to which a study meets a particular criterion – eg an acceptable level of loss to follow up – and, more importantly, the likely impact of this on the reported results from the study will depend on the clinical context. To minimise any potential bias resulting from this, each study must be evaluated independently by at least two individuals. Any differences in assessment should then be discussed by the full group. Where differences cannot be resolved, an independent reviewer will arbitrate to reach an agreed quality assessment.

7 Forming guideline recommendations

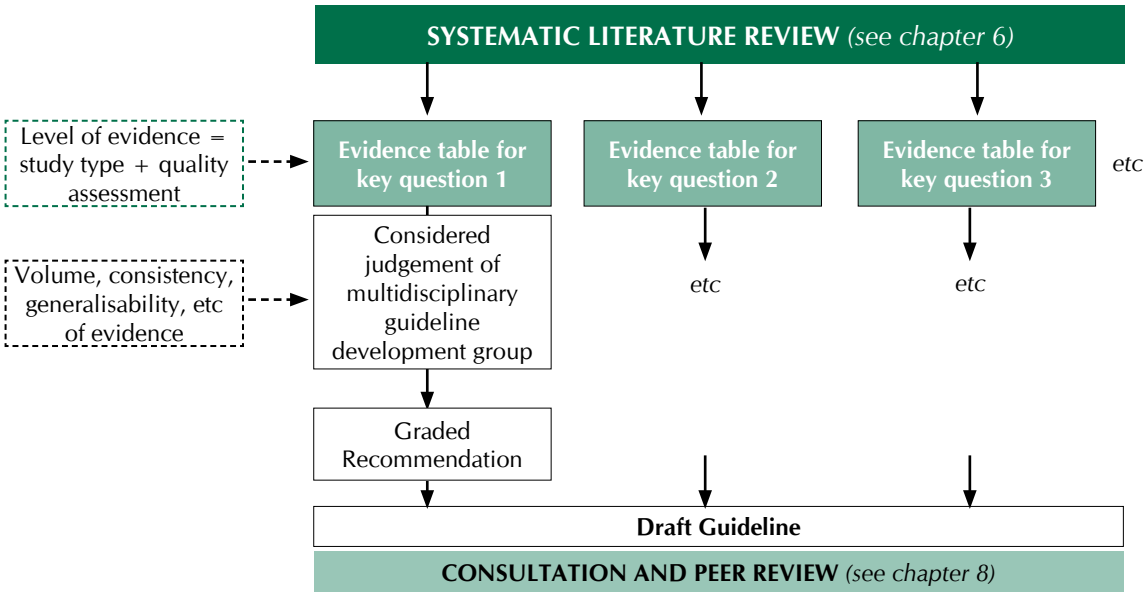
7.1 SYNTHESISING THE EVIDENCE

Guideline recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgement is made on the basis of an (objective) assessment of the design and quality of each study (as discussed in **Chapter 6**) and a (perhaps more subjective) judgement on the consistency, clinical relevance and external validity of the whole body of evidence. The aim is to produce a recommendation that is evidence based, but which is relevant to the way in which health care is delivered in Scotland and is therefore *implementable*.

It is important to emphasise that the grading does not relate to the *importance* of the recommendation **(see also Chapter 7.2.3)**, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which these data were obtained. Thus, the grading assigned to a recommendation indicates to users the likelihood that, if that recommendation is implemented, the predicted outcome will be achieved.

The process for synthesising the evidence base to form graded guideline recommendations is illustrated in Figure 11.

Figure 11: Forming guideline recommendations



Evidence tables are compiled by SIGN Executive staff based on the quality assessments of individual studies provided by guideline development group members. The tables summarise all the validated studies identified from the systematic literature review relating to each key question. They are presented in a standard format to make it easier to compare results across studies, and will present separately the evidence for each outcome measure used in the published studies. These evidence tables form an essential part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent. An example evidence table is shown in **Annex D.**

7.2 CONSIDERED JUDGEMENT

It is rare for the evidence to show clearly and unambiguously what course of action should be recommended for any given question. Consequently, it is not always clear to those who were not involved in the decision making process how guideline developers were able to arrive at their recommendations, given the evidence they had to base them on. In order to address this problem, SIGN has introduced the concept of **considered judgement**.

Under the heading of considered judgement, guideline development groups summarise their view of the total body of evidence covered by each evidence table. This summary view is split into three parts.

7.2.1 JUDGING THE LEVEL OF EVIDENCE

In the first chapter, the guideline group comments on:

- Quantity, quality, and consistency of evidence
- External validity (generalisability) of studies.
- Directness of application to the target population for the guideline.

At this point the guideline group is asked to note the overall **levels of evidence** addressing this specific key question.

7.2.2 JUDGING THE IMPACT OF THE EVIDENCE

For the next step, the guideline group is asked to consider other factors that may influence its eventual grading of a recommendation. These factors are:

- Any evidence of potential harms associated with implementation of a recommendation.
- Clinical impact (ie the extent of the impact on the target patient population, and the resources required by NHSScotland to treat them in accordance with the recommendation)
- Whether, and to what extent, any equality groups may be particularly advantaged or disadvantaged by the recommendations made.
- Implementability (ie how practical it would be for NHSScotland to implement the recommendation).

The group are finally asked to summarise its view on all of these issues, both the quality of the evidence and its potential impact, before making a graded recommendation. This summary should be succinct, and taken together with its views of the level of evidence represent the first draft of the text that will appear in the guideline immediately before a graded recommendation.

7.2.3 IDENTIFYING KEY RECOMMENDATIONS

Finally, the group is asked to consider the **importance** of the recommendation(s) it has just made. Importance is not necessarily related to strength of evidence, but should reflect the extent to which the group believes the recommendation will impact on the health status or quality of life of the patients concerned.

Where the group has indicated that a recommendation is a **key recommendation**, it is asked to provide a justification for why this recommendation should be highlighted in the final guideline. All key recommendations will be identified as such in the published guideline, and will appear in the Quick Reference Guide.

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. An example of this form and the associated notes for users is included in **Annex C**.

7.3 LEVELS OF EVIDENCE AND GRADES OF RECOMMENDATION

SIGN formerly used the levels of evidence developed by the US Agency for Health Care Policy and Research (AHCPR, now the US Agency for Health Research and Quality, AHRQ).[25] As a number of limitations were becoming apparent in that system, a review was carried out and new levels of evidence and associated grades of recommendation were developed. Following extensive consultation and international peer review, the new grading system was introduced in Autumn 2000.[26, 27] The current grading system is shown in **Annex B.**

The assignment of a level of evidence should involve all those on a particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of recommendation should involve participation of all members of the guideline development group. Where the guideline development group is unable to agree a unanimous recommendation, the difference of opinion should be formally recorded and the reasons for dissent noted.

On occasion, guideline development groups find that there is an important practical point that they wish to emphasise but for which there is not, nor is there likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it (it could be regarded as "clinical common sense"). These are shown in the guideline as Good Practice Points (GPP), and are marked ☑.

It must be emphasised that these are **not** an alternative to evidence based recommendations. Indeed, the existence of any evidence relating to a key question, however low quality it might be, excludes the possibility of using a good practice point to make a recommendation relating to that question.

Examples of how GPPs might be used include:

- Emphasising the importance of patient participation in decision making about specific procedures.
- Providing advice on the management of specific surgical procedures for which there is an evidence based recommendation
- Advising caution where there is perceived risk of harm but no available direct evidence of such harms.

The revised grading system is intended to place greater weight on the *quality* of the evidence supporting each recommendation, and to emphasise that the *body of evidence* should be considered as a whole, and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where RCTs are not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think there are important inconsistencies in the evidence base, evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest.

7.4 RESOURCE IMPLICATIONS

(This chapter is undergoing a separate detailed review and will be added shortly.)

7.5 CURRENT AREAS FOR DEVELOPMENT

The SIGN Methodology Development Group was established to consider new developments in guideline methodology, and to attempt to answer specific questions on methodological issues. It is currently looking at the following questions:

Qualitative studies as evidence: Qualitative methods are increasingly being used to inform practice in some aspects of medical care. At present, there is no mechanism for incorporating such studies in the evidence base. Some progress has been made on methods of identifying qualitative studies, and in evaluating their methodological quality. The use of qualitative evidence to identify issues of concern to patients, and to help identify key questions to be addressed in the guideline is becoming an established part of SIGN methodology. A pilot exercise looking at the formal inclusion of qualitative evidence in developing a SIGN guideline has been carried out[28] and will form the basis of future developments in this area.

Revision of the grading system: The grading system described in Chapter 7.3 is an improvement on the previous system, but still has weaknesses that need to be addressed.[29] SIGN has been participating in the international GRADE project aimed at developing a methodologically sound system that can be applied across countries and cultures.[30, 31]

Whether and to what extent the GRADE approach should be adopted by SIGN is under discussion, but whatever is decided there remains a problem in dealing with different types of evidence. GRADE addresses evidence of effectiveness where it is possible to clearly quantify benefits and harms. In other questions addressed by guidelines evidence is more likely to be presented in narrative form. As the grading system develops, means of dealing with both types of evidence in a rigorous manner will be required. Whatever changes are made are likely to be evolutionary rather than revolutionary in nature.

8 Consultation and peer review

8.1 NATIONAL OPEN MEETING

The AGREE instrument suggests that guidelines should be pilot-tested prior to publication. SIGN considers that the pilot-testing phase is more appropriately carried out at a local level as part of the local implementation process, as testing the feasibility of implementation in one environment may not be applicable to another. However, as an early stimulus to this process, SIGN holds a national open meeting to discuss the draft recommendations of each guideline. This takes place whilst the guideline is still in development and gives the guideline development group the opportunity to present its preliminary conclusions and draft recommendations to a wider audience. The benefits of the national open meeting are twofold:

1. the guideline development group obtains valuable feedback and suggestions for additional evidence which group members might consider, or alternative interpretation of that evidence
2. the participants are able to contribute to and influence the form of the final guideline, generating a sense of ownership over the guideline across geographical and disciplinary boundaries.

SIGN national open meetings are widely publicised and are usually attended by between 150 and 300 healthcare professionals and others interested in the guideline topic, including patient representatives, from across Scotland. Advertising of the meetings is targeted on those professional and patient representative groups most likely to have an interest in the topic. Particular efforts are made to ensure that all equality groups with a potential interest in the topic are represented.

The meetings are registered for CPD (Continuing Professional Development) and for EPASS (Educational Providers Accreditation Scheme Scotland) accreditation. The draft guideline is also available on the SIGN website for a month at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

The national open meeting is the main consultative phase of SIGN guideline development. Although the draft guideline is circulated to Directors of Public Health and to a number of health service organisations at a later stage, this is more as a courtesy to inform them of the likely content of the final guideline than for consultation.

8.2 PEER REVIEW

All SIGN guidelines are reviewed in draft form by independent expert referees, who are asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. A number of GPs and other primary care practitioners also provide comments on the guideline from the primary care perspective, concentrating particularly on the clarity of the recommendations and their assessment of the usefulness of the guideline as a working tool for the primary care team. The draft is also sent to at least two lay reviewers in order to obtain comments from the patient's perspective.

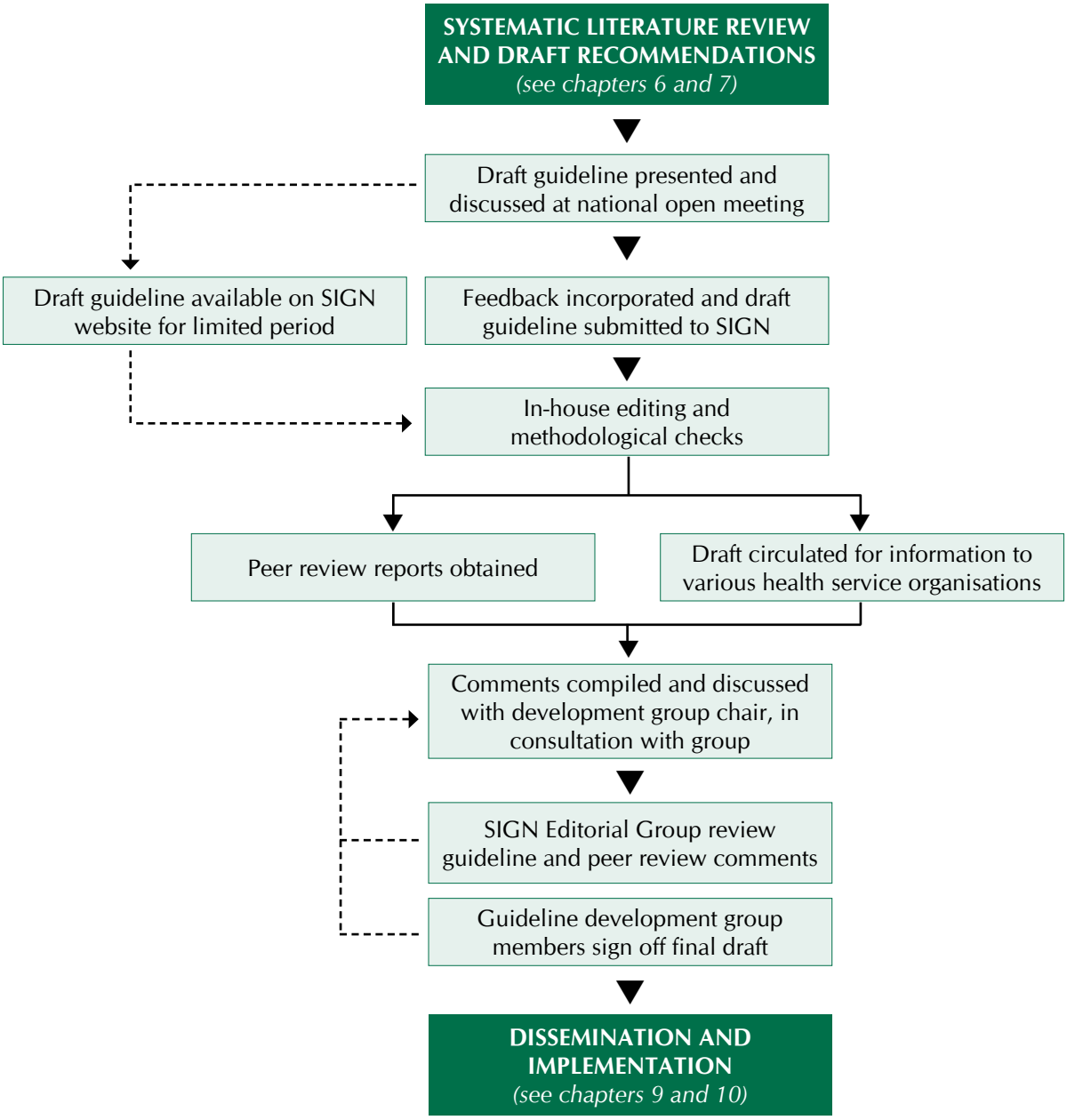
It should be noted that all reviewers are invited to comment as individuals, not as representatives of any particular organisation or group. Corporate interests, whether commercial, professional, or societal have an opportunity to make representations at the national meeting stage where they can send representatives to the meeting or provide comment on the draft produced for that meeting. Peer reviewers are asked to complete a declaration of interests form.

The comments received from peer reviewers and others are carefully tabulated and discussed with the Chair and with the guideline development group. Each point must be addressed and any changes to the guideline as a result noted or, if no change is made, the reasons for this recorded.

As a final quality control check prior to publication, the guideline and the summary of peer reviewers' comments are reviewed by the SIGN Editorial Group for that guideline to ensure that each point has been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised. Each member of the guideline development group is then asked formally to approve the final guideline for publication.

The full editorial and consultation phase is illustrated in Figure 12. This process of extended consultation greatly enhances the validity of the final SIGN guideline and increases the likelihood that the guideline will be implemented successfully into local practice for the benefit of patients.

Figure 12: Consultation and peer review



9 Presentation and dissemination

9.1 CONTENT AND PRESENTATION OF THE GUIDELINE

Guidelines with a wide range of styles and formats have been shown to be effective in changing practice. Whilst there is little information available on the effect that style and presentation have on the adoption of guidelines, clarity – of definitions, language, and format – is obviously important. Guidelines should, therefore, be written in unambiguous language and should define all terms precisely. The best format for presenting guidelines will vary depending on the target group(s), the subject matter, and the intended use of the guideline. Ideally, end users should be consulted regarding the most appropriate method of presentation for them. This is an additional function of the extensive peer review process to which all SIGN guidelines are subject **(see Chapter 8).**

Each SIGN guideline includes an introduction, outlining the need for the guideline (including evidence of variation in practice) and defining carefully the remit of the guideline, including the patient and practitioner groups to which it applies. Within the main body of the guideline, the structure should as far as possible reflect the development process that the guideline development group has followed, ie (for each chapter):

- A clear statement of the question/issue under consideration.
- A brief explanation of the treatment options available.
- A summary of the conclusions drawn from the critical appraisal of the evidence (the evidence statement, annotated with the level of evidence and key references). This should provide the justification for the recommendation to follow – ie the evidence for improved outcome resulting from the recommended action.
- The recommendations that the group has derived from this evidence (graded according to the strength of the supporting evidence).
- A brief discussion of any practical points (eg resource/geographical considerations to be taken up in the discussion of local guidelines for implementation), or outstanding treatment options for which there is no evidence (the last should be stated clearly).
- Finally, if the group feels it is important to give guidance in any of these latter areas where there is no suitable evidence, a "good practice point" may be presented.

Having a well developed and defined template for presentation of the final guideline can greatly facilitate the development process, enabling guideline development groups to plan at the outset what type of information will be required and also to envisage what format the content will take. By following the model for systematic review and formation of guideline recommendations outlined in chapters 6 and 7, guideline development groups will find that most of the required information will then be produced in a structured, accessible fomat, ready to slot into the guideline structure.

The guideline should also include key points for audit (accompanied where possible with a recommended minimum data set: **see Chapter 9.7),** suggested outcome measures, recommendations for further research, and information for patients and carers **(see Chapter 9.5**). Brief details of the systematic review on which the guideline recommendations are based is also provided, although the majority of this information is made available for reference on the SIGN website.

9.2 RECOMMENDATIONS FOR RESEARCH

SIGN guidelines themselves may act as a stimulus to research. An important subsidiary outcome of the guideline development process is in highlighting gaps in the evidence base and guidelines contain a chapter or annex listing the guideline development group's recommendations for research. The review of a guideline is an opportunity to discover whether any of the gaps in the evidence base have been filled

9.3 QUICK REFERENCE GUIDES AND KEY MESSAGES

Each SIGN guideline is published with an accompanying Quick Reference Guide (QRG). This provides a summary of the key recommendations and other information from the guideline, often following a loosely algorithmic format illustrating the recommended care pathway. The Quick Reference Guides are normally printed on the back cover of the guideline and as a separate leaflet, and have proved very popular with practitioners. It is important to note that the 'key' recommendations will not necessarily be the highest grade of recommendations (ie those with the strongest supporting evidence) but those considered by the guideline development group as having the greatest potential impact on patient care **(see Chapter 7.2.3).**

9.4 ELECTRONIC PUBLISHING

All SIGN guidelines and quick reference guides, along with any updates to guidelines, are available free of charge on the SIGN website: **www.sign.ac.uk**. With advances in access to technology, and the increasing importance of currency of information, these electronic versions are now the definitive versions of SIGN guidelines. Paper copies will continue to be produced, but it is anticipated that the number of copies printed will be substantially reduced in coming years.

9.5 INFORMATION FOR PATIENTS

All SIGN guidelines now include an 'information for patients and carers' chapter, which highlight those issues where patients and their families will most likely require information to help them understand and cope with the diagnosis, treatment options and possible outcomes. This chapter is targeted at health professionals, to help them produce local evidence based information materials although patients and carers themselves may also find this chapter useful. The issues highlighted in this chapter are informed by the:

- results of patient views gathered earlier in the development process (see **Chapter 4.2)**
- patient representatives on the development group,
- other guideline development group members.

This chapter also includes appropriate general background explanations to the clinical condition and details of appropriate help lines, support groups and reading materials.

SIGN has introduced patient versions of the guidelines. These patient versions are lay translations of the clinical guidelines and are intended to act as a tool for healthcare professionals to use when discussing management and treatment options with patients and their families. SIGN plans to carry out an evaluation of these and if results are positive they will become integrated with SIGN methodology.

As part of SIGN's commitment to the equality agenda of NHS Scotland, versions of guidelines (either full or patient versions) can be produced in the nine community languages identified by the Scottish Government, in large print, or in Signing in response to specific requests from users.

9.6 DISSEMINATION

Guidelines must obviously be made as widely available as possible in order to facilitate implementation and SIGN guidelines are distributed free of charge throughout the NHS Scotland. However, distribution of printed guidelines alone has been shown to be ineffective in achieving change in practice: guidelines are more likely to be effective if they are disseminated by an active educational intervention, and implemented by patient-specific reminders relating directly to professional activity. Distribution of SIGN guidelines in NHS Scotland is organised within each NHS Board by local distribution coordinators, who are often also responsible for facilitating implementation.

SIGN has initiated a review of its publication and dissemination processes with a view to improving the targeting of guidelines to those health care professionals most likely to find them useful.

9.7 LINKS WITH AUDIT

Development, dissemination and implementation of a guideline should be monitored and evaluated through clinical audit. During the development of the guideline, the development group identifies key points for audit. These should allow the implementation of the guideline recommendations and the impact of these on the processes and, where possible, the outcomes of care to be measured objectively. Often these process and outcome indicators are presented in the form of a minimum data set. SIGN has recently been collaborating with the Information and Statistics Division (ISD) and the Scottish Government to produce national datasets specific to guideline topics.

Clinical audit of guidelines can provide valuable information for standard setting and service accreditation. SIGN guidelines provide the evidence base for many of the national standards developed and monitored by NHS Quality Improvement Scotland. This joint approach to producing evidence based guidelines, which contain national datasets, which in turn are used to set clinical standards that are audited, should, in theory at least, improve the quality of health care delivered. Audit in turn is able to inform guideline reviews and further improve the implementation of specific recommendations.

10 Implementation

10.1 GETTING GUIDELINES INTO PRACTICE

To achieve the objective identified in Chapter 1.1 "to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances"1 it is important not only to develop valid guidelines by a sound methodology, but also to ensure the implementation of the evidence based recommendations. As one of a range of tools to help health care professionals and organisations to improve clinical effectiveness and patient outcomes **(see Chapter 1.3)**, guidelines provide an opportunity for practitioners to improve shared clinical decision-making, increase team working, expand their evidence based knowledge, and reduce variation in practice. They can also enable professionals to keep up to date and to assess their own clinical performance against the recommendations for best practice.

However, there is often a gap between the development of guidelines, as set out in the previous chapters of this handbook, and their implementation into practice. Just as guidelines themselves help provide a bridge between research and practice, this chapter outlines the strategies that can assist practitioners, and health services to bridge the gap between guideline development and implementation

10.2 IDENTIFYING BARRIERS TO IMPLEMENTATION

There are two types of barriers to the implementation of guidelines: those internal to the guideline itself, and the external barriers relating to the clinical environment and particular local circumstances. Potential external barriers to guideline implementation include:

- Structural factors (eg financial disincentives)
- Organisational factors (eg inappropriate skill mix, lack of facilities or equipment)
- Peer group (eg local standards of care not in line with desired practice)
- Individual factors (eg knowledge attitudes, skills)
- Professional-patient interaction (eg problems with information processing).

SIGN addresses the internal barriers by developing guidelines according to a highly respected methodology, described in detail in the earlier chapters. For successful implementation, the external barriers also need to be assessed and implementation strategies developed to address them.

10.3 IMPLEMENTATION INITIATIVES

Implementation of guidelines is a local responsibility and many local initiatives have already been successful in overcoming these barriers to implementation. Most clinical governance support teams in NHS Boards now have audit and clinical effectiveness facilitators with some resources to help local implementation. This is an opportunity to encourage team working and co-operation within primary and secondary care and at the interface between them.

Although its remit is limited to guideline development, SIGN seeks to facilitate guideline implementation with a number of approaches. These include wide dissemination of the guidelines at no cost to the practitioner, awareness raising initiatives and using electronic publishing to improve the availability of guidelines.

SIGN's guideline distribution policy **(see Chapter 9.6)** encourages Boards to take responsibility for local dissemination, which further promotes local awareness and opportunities for local implementation. SIGN uses the media to promote the publication of guidelines when appropriate. Members of SIGN Council are also actively involved in promoting guidelines and developing projects.

Initiatives both nationally and locally have taken into account evidence on the effectiveness of different strategies to implementation: "evidence based medicine requires evidence based implementation".[32] Implementing guidelines is not simple or straightforward. Difficulties often centre on the need for personal, organisational or cultural change.[33] However, such change is being carried through in many areas of clinical practice and information to support a local evidence based strategy is available from a variety of sources.

The Cochrane Effective Practice and Organisation of Care (EPOC) group has published a summary of 44 systematic reviews of implementation interventions, giving an indication of the most effective approaches[34] as summarised in Figure 9. The authors were quick to point out that there are "no magic bullets". Each implementation strategy is effective under certain circumstances, and a multifaceted approach is most likely to achieve change. The approach should be tailored to suit local circumstances taking into account any particular potential barriers. It is important to build in support and incentives and to consider the resources needed for successful implementation.

Figure 10.1: Effectiveness of interventions to promote implementation

Variable effectiveness	Largely effective
Audit and feedback	Reminders
Local consensus conferences	Educational outreach (for prescribing)
Opinion leader	Interactive educational workshops
Patient mediated interventions	Multi-faceted interventions

A more recent HTA review of dissemination and implementation strategies suggests that the evidence for educational outreach is equivocal and that dissemination of educational materials may have greater impact than originally considered and that multifaceted intervention comparison is problematic. The review makes it clear that there is an imperfect evidence base to support decisions about dissemination and implementation and therefore any strategy should always take account of local circumstances

Figure 10.2, adapted from Palmer and Fenner[35] and the Effective Health Care Bulletin,[34] illustrates how each strategy can be used to form part of a local implementation strategy.

10.4 PRACTICAL STEPS

The first step in this process is to prioritise the topic for the team. This may be decided by the NHS Board through their Local Health Plan, or a local service or practice may identify a priority clinical area in which they wish to examine care and identify areas for improvement. It is important to recognise that clinical teams can only tackle one guideline at a time for an active implementation strategy. Indeed it may be that only certain key recommendations within the guideline are prioritised for implementation. However the clinical team should identify the strengths and weaknesses of present provision and not merely choose those areas that are most easily implementable. It is encouraging to identify what is being done well but also important to identify where services could be improved ensuring that any changes that are planned are achievable.

Figure 10.2: Implementation strategies

Method	*Effectiveness*	*Local considerations*
Written materials	Variable findings; at best, small effect	Whilst impact is small, could be used to raise awareness of the guideline through materials or through medical journals or local publications. Useful in combination with other strategies.
Audit and feedback	Sometime effective; small to moderate effect but potentially important	This could be a valuable starting point to provide baseline information from which to develop an implementation strategy.
Education (group)	Variable effects which improve when the influence of peers is included	Identify a local multiprofessional group who can be supported with education from experts or by attending workshops or conferences. Facilitation at practice/unit level is helpful.
Education (individual)	More effective than other educational initiatives	Targeting stakeholders through individual education centred on the topic, or more general implementation issues. Consideration needs to be given to cost.
Opinion leaders	Mixed effects	Identify local and national opinion leaders and consider how they might be involved.
Product champions	No conclusive evidence	Identifying product champions might highlight innovative methods for implementation.
Academic detailing / educational outreach	Effects are small to moderate but of potential importance	Could be incorporated with individual education approach and written materials.
Mass media	May have a positive influence on how health services are used	Take advantage of mass media coverage and additionally local media sources.
Patient-mediated interventions	No conclusive research evidence	Consider local patients, consumer and pressure groups so that involvement is part of strategy at the outset
Continuous quality improvement	No conclusive research evidence	Local audit/clinical governance/ effectiveness departments should always be included in any implementation strategy.
Financial incentives	Some appear to influence practice, but not all	This may only be available for some professional groups and would depend on the nature of the guideline, eg financial support for audit, prescribing incentives.

Policy / regulation	No conclusive research evidence	National standards drawn up by NHS QIS are supported by clinical guidelines and can be influential in supporting local implementation
Reminder systems	Computerised records have supported the implementation of guidelines. Manual reminder systems were effective in many, but not all studies	Implementation may prompt a review of the record keeping system and may initiate developments such as multiprofessional integrated care pathways. Computerised decision support is being developed.
Internet / online databases	No conclusive research evidence	If local services are networked this could form a useful medium for communication and information sources
Combinations of methods	Appear to be more effective than any one intervention on its own	Importantly, a local strategy needs to consider which of the above and in what combination such strategies may be helpful

Figure 10.3 outlines the likely steps that a local implementation group might take, adapted from the Royal College of Nursing Guidelines[36] and the SPICEpc (Scottish Programme for Improving Clinical Effectiveness in Primary Care) project **(www.ceppc.org/spice/index.shtml).**

Figure 10.3: Practical steps towards guideline implementation

Step 1

Decide who will lead and coordinate the team and identify stakeholder representatives for the implementation group. It is often helpful to have a key facilitator for this process. The team should be multiprofessional in composition.

Step 2

Determine the current position. It is essential to be aware of current practice and to identify where changes need to be made. It is helpful to audit current clinical practice. It is also important to review the local environment considering people, systems, structures and internal and external influences. Through this process it is possible to identify potential barriers and facilitators to implementation.

Step 3

Prepare the people and the environment for guideline implementation. It is important to ensure that the professionals are receptive with a positive attitude to the initiative and have the skills and knowledge to carry out the procedures. This requires time, enthusiasm and commitment with good communication and offers of tangible help. It is important also to involve patient groups in planning the initiative so they are involved from the outset and can influence the way that the guideline is implemented into local services. It is important to take into account patient preferences and views eg Scottish Health Council publications, local surveys. In preparing the environment it may be necessary to acquire new equipment or change forms or access services in a different way. It may be possible to consider the inclusion of reminder notes or computer assisted reminders.

Step 4

Decide which implementation techniques to use to promote the use of the clinical guidelines in practice. This should take into account the potential barriers already identified and use the research evidence on effective strategies.

Step 5

Pulling it all together. This requires an action plan for the improvement process. It requires everyone to agree the aims with a named person responsible for the action plan; a time scale identified with contingency plans to deal with any problems along the way.

Step 6

Evaluate progress through regular audit and review with feedback to the team. Rewarding achievements is important. Plans may be required to be modified in the light of difficulties or surprises found during the implementation process. It is always important though to celebrate successes and aim for small achievable steps along the way to improve the quality of patient care.

10.5 MONITORING IMPLEMENTATION

Monitoring of guideline implementation is one of the responsibilities of NHS Quality Improvement Scotland (NHS QIS). NHS QIS clinical standards focus on clinical issues and are evidence based, although levels and types of evidence vary. Where possible they are based on standards drawn from SIGN and other evidence based guidelines as well as good practice statements.

Annex A

Register of interests – fictitious example

Having read the attached SIGN Policy on Declaration of Competing Interests I declare the following competing interests for the previous year, and the following year. I understand that this declaration will be retained by the SIGN Administrator for 5 years, and made available for public inspection at the SIGN Office

Signature:				
Name:	Lindsay Brown			
Relationship to SIGN:	Member of Guideline Development Group on bronchiolitis			
Personal interests				
This section relates to interests of the person concerned. For their partners or close relatives, interests are restricted to employment in, or share holdings in, healthcare organisations. **Specific interests are those which relate to a topic or remit of the particular guideline. Non specific interests are those which are otherwise relevant to the work of SIGN.**				
Remuneration from employment				
	Name of Employer and Post held	**Nature of Business**	**Self or partner / relative**	**SPECIFIC?**
Details of Employment held which may be significant to, or relevant to, or bear upon the work of SIGN	Consultant Bogside NHS Trust Sales Representative for Ultra (antiviral drug) Aviemore Pharmaceuticals PLC	Medical Practitioner Manufacture of antiviral drugs used in paediatric conditions	Self Partner	No Yes
Remuneration from self-employment				
	Name of Business	**Nature of Business**	**Self or partner / relative**	**SPECIFIC?**
Details of self-employment held which may be significant to, or relevant to, or bear upon the work of SIGN	Bogside Physiotherapy Practice	Private physiotherapy practice	Daughter	Yes

Remuneration as holder of paid office				
	Nature of Office held	**Organisation**	**Self or partner / relative**	**SPECIFIC?**
Details of office held which may be significant to, or relevant to, or bear upon the work of SIGN	Organist, St Elsewhere's Church	Church of St Elsewhere	Self	No
Remuneration as a director of an undertaking				
	Name of Undertaking	**Nature of Business**	**Self or partner / relative**	**SPECIFIC?**
Details of directorship held which may be significant to, or relevant to, or bear upon the work of SIGN	Bogside Private Hospice	Non executive Director	Self	No
Remuneration as a partner in a firm				
	Name of Partnership	**Nature of Business**	**Self or partner / relative**	**SPECIFIC?**
Details of Partnership held which may be significant to, or relevant to, or bear upon the work of SIGN	Bogside Computer Games Ltd	Software development	Brother	No
Shares and securities				
	Description of organisation	**Description of nature of holding** (value need not be disclosed)	**Self or partner / relative**	**SPECIFIC?**
Details of interests in shares and securities in commercial healthcare companies, organisations and undertakings	Mega oxygen Supplies PLC	Shares	Self	Yes
	Glastonbury Pharmaceuticals PLC	Shares	Partner	No
Remuneration from consultancy or other fee paid work commissioned by, or gifts or support from, commercial healthcare companies, organisations and undertakings				
	Nature of work	**For whom undertaken and frequency**	**Self or partner / relative**	**SPECIFIC?**
Details of consultancy or other fee paid work which may be significant to, or relevant to, or bear upon the work of SIGN	Consultancy	Ozone Inc (manufacturer of ventilators) 2 days / year	Self	Yes
	Lecturing on terminal care	Lecture fee paid by Exit Inc. (once only)	Self	No

Details of gifts which may be significant to, or relevant to, or bear upon the work of SIGN	Personal computer	Exit Inc.	Self	No
Details of support to attend meetings / conferences which may be significant to, or relevant to, or bear upon the work of SIGN	Travel and conference fees to attend annual paediatric respiratory forums	Ozone Inc	Self	Yes
Non-financial interests				
	Description of interest	**Self or partner / relative**	**SPECIFIC?**	
Details of non-financial interests which may be significant to, or relevant to, or bear upon the work of SIGN	Member of Bronchosupport, Bogside (charitable support group)	Self	Yes	
Non personal interests				
This chapter relates to support from healthcare companies to departmental / employer / business for research and audit activities, travel and subsistence for conferences, etc.				
	Name of company, organisation or undertaking	**Nature of interest**	**Self or partner / relative**	**SPECIFIC?**
Details of non-personal support from commercial healthcare companies, organisations or undertakings.	Universal Pharmaceuticals PLC	Departmental support for research nurse (2 sessions / week) performing clinical trials of physiotherapy in bronchiolitis	Self	Specific
	Nairn Pharmaceutics PLC	Departmental support for Registrar's travel to meeting of European Society of Palliative Care (Self, non specific)	Self	Non specific
DATE RECEIVED AT SIGN:				

Annex B

Key to evidence statements and grades of recommendations

LEVELS OF EVIDENCE

1 + + High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias

1 + Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

1 - Meta-analyses, systematic reviews, or RCTs with a high risk of bias

2 + + High quality systematic reviews of case control or cohort studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2 + Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2 - Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3 Non-analytic studies, eg case reports, case series

4 Expert opinion

GRADES OF RECOMMENDATION

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A At least one meta-analysis, systematic review, or RCT rated as 1 + +, and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1 +, directly applicable to the target population, and demonstrating overall consistency of results

B A body of evidence including studies rated as 2 + +, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1 + + or 1 +

C A body of evidence including studies rated as 2 +, directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2 + +

D Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2 +

GOOD PRACTICE POINTS

☑ Recommended best practice based on the clinical experience of the guideline development group.

Annex C

METHODOLOGY CHECKLIST 1: SYSTEMATIC REVIEWS AND META-ANALYSES			
Study identification (*Include author, title, year of publication, journal title, pages*)			
Guideline topic:		Key Question No:	
Checklist completed by:			
SECTION 1: INTERNAL VALIDITY			
In a well conducted systematic review		**In this study this criterion is::**	
1.1	The study addresses an appropriate and clearly focused question.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.2	A description of the methodology used is included.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.4	Study quality is assessed and taken into account.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.5	There are enough similarities between the studies selected to make combining them reasonable.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
SECTION 2: OVERALL ASSESSMENT OF THE STUDY			
2.1	How well was the study done to minimise bias? Code + +, +, or –		
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?		

SECTION 3: DESCRIPTION OF THE STUDY Please print answers clearly		
3.1	What types of study are included in the review? *(Highlight all that apply)*	RCT CCT Cohort Case-control Other
3.2	How does this review help to answer your key question? *Summarise the main conclusions of the review and how it relates to the relevant key question. Comment on any particular strengths or weaknesses of the review as a source of evidence for a guideline produced for the NHS in Scotland.*	

NOTES ON THE USE OF METHODOLOGY CHECKLIST 1: SYSTEMATIC REVIEWS AND META-ANALYSES

Section 1 identifies the study, the reviewer, the guideline for which the paper is being considered as evidence, and the key question(s) it is expected to address. The reviewer is asked to consider a series of aspects of study design and to make a judgement as to how well the current study meets each criterion. Each relates to an aspect of methodology that research has shown to be likely to influence the conclusions of a study.

For each question in this section you should use one of the following to indicate how well it has been addressed in the study:

- Well covered
- Adequately addressed
- Poorly addressed
- Not addressed (i.e. not mentioned, or indicates that this aspect of study design was ignored)
- Not reported (i.e. mentioned, but insufficient detail to allow assessment to be made)
- Not applicable.

1.1 The study addresses an appropriate and clearly focused question.

Unless a clear and well defined question is specified in the report of the review, it will be difficult to assess how well it has met its objectives or how relevant it is to the question you are trying to answer on the basis of the conclusions.

1.2 A description of the methodology used is included.

One of the key distinctions between a systematic review and a general review is the systematic methodology used. A systematic review should include a detailed description of the methods used to identify and evaluate individual studies. If this description is not present, it is not possible to make a thorough evaluation of the quality of the review, and it should be rejected as a source of Level 1 evidence. (Though it may be useable as Level 4 evidence, if no better evidence can be found.)

1.3 The literature search is sufficiently rigorous to identify all the relevant studies.

A systematic review based on a limited literature search – e.g. one limited to Medline only – is likely to be heavily biased. A well conducted review should as a minimum look at Embase and Medline, and from the late 1990s onward, the Cochrane Library. Any indication that hand searching of key journals, or follow up of reference lists of included studies were carried out in addition to electronic database searches can be taken as evidence of a well conducted review.

1.4 Study quality is assessed and taken into account.

A well conducted systematic review should have used clear criteria to assess whether individual studies had been well conducted before deciding whether to include or exclude them. If there is no indication of such an assessment, the individual papers included in the review must be obtained and their methodology evaluated.

1.5 There are enough similarities between the studies selected to make combining them reasonable.

Studies covered by a systematic review should be selected using clear inclusion criteria. These criteria should include, either implicitly or explicitly, the question of whether the selected studies can legitimately be compared. It should be clearly ascertained, for example, that the populations covered by the studies are comparable; that the methods used in the investigations are the same; that the outcome measures are comparable; and the variability in effect sizes between studies is not greater than would be expected by chance alone.

Section 2 relates to the overall assessment of the paper. Question 2.1 asks you to rate the methodological quality of the study, based on your responses in Section 1 and using the following coding system:

+ +

All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought **very unlikely** to alter.

+

Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought **unlikely** to alter the conclusions.

-

Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to alter.

The code allocated here, coupled with the study type, will decide the level of evidence that this study provides.

Question 2.2 asks you to indicate whether a review with poor or relatively poor methodology is likely to overstate or understate any effect identified.

Section 3 asks you to identify the types of study covered by the review, and to provide a brief summary of the conclusions of the review as well as your own view of its strengths and weaknesses, and how it will help to answer the key question.

METHODOLOGY CHECKLIST 2: RANDOMISED CONTROLLED TRIALS			
Study identification (Include author, title, year of publication, journal title, pages)			
Guideline topic:		Key Question No:	
Checklist completed by:			
SECTION 1: INTERNAL VALIDITY			
In a well conducted RCT study…		***In this study this criterion is:***	
1.1	The study addresses an appropriate and clearly focused question.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.2	The assignment of subjects to treatment groups is randomised	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.3	An adequate concealment method is used	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.5	The treatment and control groups are similar at the start of the trial	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.6	The only difference between groups is the treatment under investigation	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?		
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable

SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimise bias? Code + +, +, or –	
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	
2.4	Are the results of this study directly applicable to the patient group targeted by this guideline?	
SECTION 3: DESCRIPTION OF THE STUDY *(The following information is required to complete evidence tables facilitating cross-study comparisons. Please complete all sections for which information is available).* PLEASE PRINT CLEARLY		
3.1	How many patients are included in this study? Please indicate number in each arm of the study, at the time the study began.	
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics - e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	
3.4	What comparisons are made in the study? Are comparisons made between treatments, or between treatment and placebo / no treatment?	
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study - e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	

NOTES ON THE USE OF METHODOLOGY CHECKLIST 2: RANDOMISED CONTROLLED TRIALS

Section 1 identifies the study, the reviewer, the guideline for which the paper is being considered as evidence, and the key question(s) it is expected to address. The reviewer is asked to consider a series of aspects of RCT design and to make a judgement as to how well the current study meets this criterion. Each relates to an aspect of methodology that research has shown makes a significant difference to the conclusions of a study.

For each question in this section you should use one of the following to indicate how well it has been addressed in the study:

- Well covered
- Adequately addressed
- Poorly addressed
- Not addressed (i.e. not mentioned, or indicates that this aspect of study design was ignored)
- Not reported (i.e. mentioned, but insufficient detail to allow assessment to be made)
- Not applicable.

1.1 The study addresses an appropriate and clearly focused question

Unless a clear and well defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.

1.2 The assignment of subjects to treatment groups randomised

Random allocation of patients to receive one or other of the treatments under investigation, or to receive either treatment or placebo, is fundamental to this type of study. **If there is no indication of randomisation, the study should be rejected**. If the description of randomisation is poor, the study should be given a lower quality rating. Processes such as alternate allocation, allocation by date of birth, or day of the week attending a clinic are not true randomisation processes and it is easy for a researcher to work out which patients received which treatment. These studies should therefore be classed as Controlled Clinical Trials rather than RCTs.

1.3 An adequate concealment method is used

Allocation concealment refers to the process used to ensure that researchers are unaware which group patients are being allocated to at the time they enter the study. Research has shown that where allocation concealment is inadequate, investigators can overestimate the effect of interventions by up to 40%. Centralised allocation, computerised allocation systems, or the use of coded identical containers would all be regarded as adequate methods of concealment, and may be taken as indicators of a well conducted study. If the method of concealment used is regarded as poor, or relatively easy to subvert, the study must be given a lower quality rating, and can be rejected if the concealment method is seen as inadequate.

1.4 Subjects and investigators are kept 'blind' to treatment allocation

Blinding refers to the process whereby people are kept unaware of which treatment an individual patient has been receiving when they are assessing the outcome for that patient. It can be carried out up to three levels. Single blinding is where patients are unaware of which treatment they are receiving. In double blind studies neither the doctor nor the patient knows which treatment is being given. In very rare cases studies may be triple blinded, where neither patients, doctors, nor those conducting the analysis are aware of which patients received which treatment. The higher the level of blinding, the lower the risk of bias in the study.

1.5 The treatment and control groups were similar at the start of the trial

Patients selected for inclusion in a trial must be as similar as possible. The study should report any significant differences in the composition of the study groups in relation to gender mix, age, stage of disease (if appropriate), social background, ethnic origin, or comorbid conditions. These factors may be covered by inclusion and exclusion criteria, rather than being reported directly. Failure to address this question, or the use of inappropriate groups, should lead to the study being downgraded.

1.6 The only difference between the groups is the treatment under investigation

If some patients received additional treatment, even if of a minor nature or consisting of advice and counselling rather than a physical intervention, this treatment is a potential confounding factor that may invalidate the results. **If groups were not treated equally, the study should be rejected unless no other evidence is available**. If the study is used as evidence it should be treated with caution.

1.7 All relevant outcomes measured in a standard, valid and reliable way

The primary outcome measures used should be clearly stated in the study. **If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected**. Where outcome measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study.

1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?

The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop out rate is regarded as acceptable, but this may vary. Some regard should be paid to why patients dropped out, as well as how many. It should be noted that the drop out rate may be expected to be higher in studies conducted over a long period of time. A higher drop out rate will normally lead to downgrading, rather than rejection of a study.

1.9 All the subjects are analysed in the groups to which they were randomly allocate (intention to treat analysis)

In practice, it is rarely the case that all patients allocated to the intervention group receive the intervention throughout the trial, or that all those in the comparison group do not. Patients may refuse treatment, or contra-indications arise that lead them to be switched to the other group. If the comparability of groups through randomisation is to be maintained, however, patient outcomes must be analysed according to the group to which they were originally allocated irrespective of the treatment they actually received. (This is known as intention to treat analysis.) If it is clear that analysis was not on an intention to treat basis, the study may be rejected. If there is little other evidence available, the study may be included but should be evaluated as if it were a non-randomised cohort study.

1.10 Where the study is carried out at more than one site, results are comparable for all sites

In multi-site studies, confidence in the results should be increased if it can be shown that similar results were obtained at the different participating centres.

Section 2 relates to the overall assessment of the paper. It starts by rating the methodological quality of the study, based on your responses in Section 1 and using the following coding system:

++

All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought **very unlikely** to alter.

+

Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought **unlikely** to alter the conclusions.

-

Few or no criteria fulfilled. The conclusions of the study are thought **likely or very likely** to alter.

The code allocated here, coupled with the study type, will decide the level of evidence that this study provides.

The aim of the other questions in this section is to summarise your view of the quality of this study and its applicability to the patient group targeted by the guideline you are working on.

Section 3 asks you to summarise key points about the study that will be added to an evidence table at the next stage of the process. **It is important that you complete this section as fully as possible, and include actual data from the study wherever relevant.**

METHODOLOGY CHECKLIST 3: COHORT STUDIES			
Study identification (*Include author, title, year of publication, journal title, pages*)			
Guideline topic:		Key Question No:	
Checklist completed by:			
SECTION 1: INTERNAL VALIDITY			
In a well conducted cohort study...		***In this study the criterion is:***	
1.1	The study addresses an appropriate and clearly focused question.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
SELECTION OF SUBJECTS			
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.3	The study indicates how many of the people asked to take part did so, in each of the groups being studied.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed.		
1.6	Comparison is made between full participants and those lost to follow up, by exposure status.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
ASSESSMENT			
1.7	The outcomes are clearly defined.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.8	The assessment of outcome is made blind to exposure status.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.9	Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable

1.10	The measure of assessment of exposure is reliable.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.11	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.12	Exposure level or prognostic factor is assessed more than once.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
CONFOUNDING			
1.13	The main potential confounders are identified and taken into account in the design and analysis.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
STATISTICAL ANALYSIS			
1.14	Confidence intervals are provided	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
SECTION 2: OVERALL ASSESSMENT OF THE STUDY			
2.1	How well was the study done to minimise the risk of bias or confounding, and to establish a causal relationship between exposure and effect? Code + +, +, or −		
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the exposure being investigated?		
2.3	Are the results of this study directly applicable to the patient group targeted in this guideline?		

SECTION 3: DESCRIPTION OF THE STUDY ***(Note: The following information is required for evidence tables to facilitate cross-study comparisons. Please complete all sections for which information is available).*** **PLEASE PRINT CLEARLY**		
3.1	How many patients are included in this study? *List the number in each group separately*	
3.2	What are the main characteristics of the study population? *Include all relevant characteristics - e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	
3.3	What environmental or prognostic factor is being investigated in this study?	
3.4	What comparisons are made in the study? *Are comparisons made between presence or absence of an environmental / prognostic factor, or different levels of the factor?*	
3.5	For how long are patients followed-up in the study?.	
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess the impact of the chosen environmental or prognostic factor.*	
3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study - e.g. absolute or relative risk. Include p values and any confidence intervals that are provided.* ***Note****: Be sure to include any adjustments made for confounding factors, differences in prevalence, etc.*	
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.?*	

NOTES ON THE USE OF METHODOLOGY CHECKLIST 3: COHORT STUDIES

The studies covered by this checklist are designed to answer questions of the type "What are the effects of this exposure?", It relates to studies that compare a group of people with a particular exposure with another group who either have not had the exposure, or have a different level of exposure. Cohort studies may be prospective (where the exposure is defined and subjects selected before outcomes occur), or retrospective (where exposure is assessed after the outcome is known, usually by the examination of medical records). Retrospective studies are generally regarded as a weaker design, and should not receive a "++" rating.

Section 1 identifies the study, the reviewer, the guideline for which the paper is being considered as evidence, and the key question(s) it is expected to address. The reviewer is asked to consider a series of aspects of cohort study design and to make a judgement as to how well the current study meets this criterion. Each relates to an aspect of methodology that research has shown to be likely to influence the conclusions of a study

Because of the potential complexity and subtleties of the design of this type of study, there are comparatively few criteria that automatically rule out use of a study as evidence. It is more a matter of increasing confidence in the strength of association between exposure and outcome by identifying how many aspects of good study design are present, and how well they have been tackled. A study that fails to address or report on more than one or two of the questions addressed below should almost certainly be rejected.

For each question in this section you should use one of the following to indicate how well it has been addressed in the study:

- Well covered
- Adequately addressed
- Poorly addressed
- Not addressed (i.e. not mentioned, or indicates that this aspect of study design was ignored)
- Not reported (i.e. mentioned, but insufficient detail to allow assessment to be made)
- Not applicable.

1.1 The study addresses an appropriate and clearly focused question?

Unless a clear and well defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.

1.2 The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.

It is important that the two groups selected for comparison are as similar as possible in all characteristics except for their exposure status, or the presence of specific prognostic factors or prognostic markers relevant to the study in question. **If the study does not include clear definitions of the source populations and eligibility criteria for participants it should be rejected.**

1.3 The study indicates how many of the people asked to take part did so, in each of the groups being studied.

The participation rate is defined as the number of study participants divided by the number of eligible subjects, and should be calculated separately for each branch of the study. A large difference in participation rate between the two arms of the study indicates that a significant degree of selection bias may be present, and the study results should be treated with considerable caution.

1.4 The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis?

If some of the eligible subjects, particularly those in the unexposed group, already have the outcome at the start of the trial the final result will be biased. A well conducted study will attempt to estimate the likelihood of this occurring, and take it into account in the analysis through the use of sensitivity studies or other methods.

1.5 What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed?

The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop out rate is regarded as acceptable, but in observational studies conducted over a lengthy period of time a higher drop out rate is to be expected. A decision on whether to downgrade or reject a study because of a high drop out rate is a matter of judgement based on the reasons why people dropped out, and whether drop out rates were comparable in the exposed and unexposed groups. Reporting of efforts to follow up participants that dropped out may be regarded as an indicator of a well conducted study.

1.6 Comparison is made between full participants and those lost to follow-up, by exposure status.

For valid study results, it is essential that the study participants are truly representative of the source population. It is always possible that participants who dropped out of the study will differ in some significant way from those who remained part of the study throughout. A well conducted study will attempt to identify any such differences between full and partial participants in both the exposed and unexposed groups. Any indication that differences exist, should lead to the study results being treated with caution.

1.7 The outcomes are clearly defined.

Once enrolled in the study, participants should be followed until specified end points or outcomes are reached. In a study of the effect of exercise on the death rates from heart disease in middle aged men, for example, participants might be followed up until death, or until reaching a predefined age. **If outcomes and the criteria used for measuring them are not clearly defined, the study should be rejected**.

1.8 The assessment of outcome is made blind to exposure status

If the assessor is blinded to which participants received the exposure, and which did not, the prospects of unbiased results are significantly increased. Studies in which this is done should be rated more highly than those where it is not done, or not done adequately.

1.9 Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.

Blinding is not possible in many cohort studies. In order to asses the extent of any bias that may be present, it may be helpful to compare process measures used on the participant groups – e.g. frequency of observations, who carried out the observations, the degree of detail and completeness of observations. If these process measures are comparable between the groups, the results may be regarded with more confidence.

1.10 The measure of assessment of exposure is reliable.

A well conducted study should indicate how the degree of exposure or presence of prognostic factors or markers was assessed. Whatever measures are used must be sufficient to establish clearly that participants have or have not received the exposure under investigation and the extent of such exposure, or that they do or do not possess a particular prognostic marker or factor. Clearly described, reliable measures should increase the confidence in the quality of the study.

1.11 Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.

The primary outcome measures used should be clearly stated in the study. **If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected.** Where outcome measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study.

1.12 Exposure level or prognostic factor is assessed more than once

Confidence in data quality should be increased if exposure level is measured more than once in the course of the study. Independent assessment by more than one investigator is preferable.

1.13 The main potential confounders are identified and taken into account adequately in the design and analysis.

Confounding is the distortion of a link between exposure and outcome by another factor that is associated with both exposure and outcome. The possible presence of confounding factors is one of the principal reasons why observational studies are not more highly rated as a source of evidence. The report of the study should indicate which potential confounders have been considered, and how they have been assessed or allowed for in the analysis. Clinical judgement should be applied to consider whether all likely confounders have been considered. If the measures used to address confounding are considered inadequate, the study should be downgraded or rejected, depending on how serious the risk of confounding is considered to be. **A study that does not address the possibility of confounding should be rejected.**

1.14 Confidence intervals are provided

Confidence limits are the preferred method for indicating the precision of statistical results, and can be used to differentiate between an inconclusive study and a study that shows no effect. Studies that report a single value with no assessment of precision should be treated with extreme caution.

Section 2 relates to the overall assessment of the paper. It starts by rating the methodological quality of the study, based on your responses in Section 1 and using the following coding system:

++

All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought **very unlikely** to alter.

+

Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought **unlikely** to alter the conclusions.

-

Few or no criteria fulfilled. The conclusions of the study are thought **likely or very likely** to alter.

The code allocated here, coupled with the study type, will decide the level of evidence that this study provides.

The aim of the other questions in this section is to summarise your view of the quality of this study and its applicability to the patient group targeted by the guideline you are working on.

Section 3 asks you to summarise key points about the study that will be added to an evidence table at the next stage of the process. **It is important that you complete this section as fully as possible, and include actual data from the study wherever relevant.**

METHODOLOGY CHECKLIST 4: CASE-CONTROL STUDIES			
Study identification (*Include author, title, year of publication, journal title, pages*)			
Guideline topic:		Key Question No:	
Checklist completed by:			
SECTION 1: INTERNAL VALIDITY			
In a well conducted case control study...		***In this study the criterion is:***	
1.1	The study addresses an appropriate and clearly focused question	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
SELECTION OF SUBJECTS			
1.2	The cases and controls are taken from comparable populations	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.3	The same exclusion criteria are used for both cases and controls	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.4	What percentage of each group (cases and controls) participated in the study?	Cases: Controls:	
1.5	Comparison is made between participants and non-participants to establish their similarities or differences	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.6	Cases are clearly defined and differentiated from controls	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.7	It is clearly established that controls are non-cases	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
ASSESSMENT			
1.8	Measures will have been taken to prevent knowledge of primary exposure influencing case ascertainment	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.9	Exposure status is measured in a standard, valid and reliable way	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
CONFOUNDING			
1.10	The main potential confounders are identified and taken into account in the design and analysis	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable

STATISTICAL ANALYSIS		
1.11	Confidence intervals are provided	
SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimise the risk of bias or confounding? Code + +, +, or –	
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the exposure being investigated?	
2.3	Are the results of this study directly applicable to the patient group targeted by this guideline?	

SECTION 3: DESCRIPTION OF THE STUDY ***(Note:The following information is required for evidence tables to facilitate cross-study comparisons. Please complete all sections for which information is available).*** **PLEASE PRINT CLEARLY**		
3.1	How many patients are included in this study? *List the number cases and controls separately*	
3.2	What are the main characteristics of the study population? *Include all characteristics used to identify both cases and controls - e.g. age, sex, social class, disease status*	
3.3	What environmental or prognostic factor is being investigated in this study?	
3.4	What comparisons are made in the study? *Normally only one factor will be compared, but in some cases the extent of exposure may be stratified - e.g. non-smokers v. light, moderate, or heavy smokers. Note all comparisons here.*	
3.5	For how long are patients followed-up in the study? *Length of time participant histories are tracked in the study.*	
3.6	What outcome measures are used in the study? *List all outcomes that are used to assess the impact of the chosen environmental or prognostic factor.*	

3.7	What size of effect is identified in the study? *Effect size should be expressed as an odds ratio. If any other measures are included, note them as well. Include p values and any confidence intervals that are provided.*	
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.?*	

NOTES ON THE USE OF METHODOLOGY CHECKLIST 4: CASE-CONTROL STUDIES

The studies covered by this checklist are designed to answer questions of the type "What are the factors that caused this event?", and involve comparison of individuals with an outcome with other individuals from the same population who do not have the outcome. These studies start after the outcome of an event, and can be used to assess multiple causes of a single event. They are generally used to assess the causes of a new problem, but may also be useful for the evaluation of population based interventions such as screening.

Section 1 identifies the study, the reviewer, the guideline for which the paper is being considered as evidence, and the key question(s) it is expected to address. The reviewer is asked to consider a series of aspects of cohort study design and to make a judgement as to how well the current study meets this criterion. Each relates to an aspect of methodology that research has shown makes a significant difference to the conclusions of a study.

Case-control studies need to be very carefully designed, and the complexity of their design is often not appreciated by investigators, leading to many poor quality studies being conducted. The questions in this checklist are designed to identify the main features that should be present in a well designed study. There are few criteria that should, alone and unsupported, lead to rejection of a study. However, a study that fails to address or report on more than one or two of the questions addressed below should almost certainly be rejected.

For each question in this section you should use one of the following to indicate how well it has been addressed in the study:

- Well covered
- Adequately addressed
- Poorly addressed
- Not addressed (i.e. not mentioned, or indicates that this aspect of study design was ignored)
- Not reported (i.e. mentioned, but insufficient detail to allow assessment to be made)
- Not applicable.

1.1 The study addresses an appropriate and clearly focused question

Unless a clear and well defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.

1.2 The cases and controls are taken from comparable populations.

Study participants may be selected from the target population (all individuals to which the results of the study could be applied), the source population (a defined subset of the target population from which participants are selected), or from a pool of eligible subjects (a clearly defined and counted group selected from the source population. **If the study does not include clear definitions of the source population it should be rejected.**

1.3 The same exclusion criteria are used for both cases and controls

All selection and exclusion criteria should be applied equally to cases and controls. Failure to do so may introduce a significant degree of bias into the results of the study.

1.4 What percentage of each group (cases and controls) participated in the study?

Differences between the eligible population and the participants are important, as they may influence the validity of the study. A participation rate can be calculated by dividing the number of study participants by the number of eligible subjects. It is more useful if calculated separately for cases and controls. If the participation rate is low, or there is a large difference between the two groups, the study results may well be invalid due to differences between participants and non-participants. In these circumstances, the study should be downgraded, and rejected if the differences are very large.

1.5 Comparison is made between participants and non-participants to establish their similarities or differences

Even if participation rates are comparable and acceptable, it is still possible that the participants selected to act as cases or controls may differ from other members of the source population in some significant way. A well conducted case-control study will look at samples of the non-participants among the source population to ensure that the participants are a truly representative sample.

1.6 Cases are clearly defined and differentiated from controls

The method of selection of cases is of critical importance to the validity of the study. Investigators have to be certain that cases are truly cases, but must balance this with the need to ensure that the cases admitted into the study are representative of the eligible population. **The issues involved in case selection are complex, and should ideally be evaluated by someone with a good understanding of the design of case-control studies. If the study does not comment on how cases were selected, it is probably safest to reject it as a source of evidence.**

1.7 It is clearly established that controls are non-cases

Just as it is important to be sure that cases are true cases, it is important to be sure that controls do not have the outcome under investigation. Control subjects should be chosen so that information on exposure status can be obtained or assessed in a similar way to that used for the selection of cases. If the methods of control selection are not described, the study should be rejected. **If different methods of selection are used for cases and controls the study should be evaluated by someone with a good understanding of the design of case-control studies.**

1.8 Measures will have been taken to prevent knowledge of primary exposure influencing case ascertainment

If there is a possibility that case ascertainment can be influenced by knowledge of exposure status, assessment of any association is likely to be biased. A well conducted study should take this into account in the design of the study.

1.9 Exposure status is measured in a standard, valid and reliable way

The primary outcome measures used should be clearly stated in the study. **If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected.** Where outcome measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study.

1.10 The main potential confounders are identified and taken into account in the design and analysis

Confounding is the distortion of a link between exposure and outcome by another factor that is associated with both exposure and outcome. The possible presence of confounding factors is one of the principal reasons why observational studies are not more highly rated as a source of evidence. The report of the study should indicate which potential confounders have been considered, and how they have been assessed or allowed for in the analysis. Clinical judgement should be applied to consider whether all likely confounders have been considered. If the measures used to address confounding are considered inadequate, the study should be downgraded or rejected, depending on how serious the risk of confounding is considered to be. **A study that does not address the possibility of confounding should be rejected.**

1.11 Confidence intervals are provided

Confidence limits are the preferred method for indicating the precision of statistical results, and can be used to differentiate between an inconclusive study and a study that shows no effect. Studies that report a single value with no assessment of precision should be treated with extreme caution.

Section 2 relates to the overall assessment of the paper. It starts by rating the methodological quality of the study, based on your responses in Section 1 and using the following coding system:

++

All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought **very unlikely** to alter.

+

Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought **unlikely** to alter the conclusions.

-

Few or no criteria fulfilled. The conclusions of the study are thought **likely or very likely** to alter.

The code allocated here, coupled with the study type, will decide the **level of evidence** that this study provides.

The aim of the other questions in this section is to summarise your view of the quality of this study and its applicability to the patient group targeted by the guideline you are working on.

Section 3 asks you to summarise key points about the study that will be added to an evidence table at the next stage of the process. **It is important that you complete this section as fully as possible, and include actual data from the study wherever relevant.**

METHODOLOGY CHECKLIST 5: STUDIES OF DIAGNOSTIC ACCURACY			
This checklist and the associated notes are based on the QADAS tool: Whiting J, Rutjes AW, Dinnes J, Reitsma JB, Bossuyt PM, Kleijnen J. Development and validation of methods for assessing the quality of diagnostic accuracy studies. Health Tech Assess 2004;8(25).			
Study identification (Include author, title, reference, year of publication)			
Guideline topic:		Key Question No:	
Checklist completed by:			
SECTION 1: INTERNAL VALIDITY			
In a well conducted diagnostic study…		***In this study this criterion is***	
1.1	The spectrum of patients is representative of the patients who will receive the test in practice.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.2	Selection criteria are clearly described.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.3	The reference standard is likely to classify the condition correctly.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.4	The period between reference standard and index test is short enough to be reasonably sure that the target condition did not change between the two tests.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.5	The whole sample, or a random selection of the sample, received verification using a reference standard of diagnosis.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.6	Patients received the same reference standard regardless of the index test result.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.7	The reference standard was independent of the index test (i.e. the index test did not form part of the reference standard).	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.8	The execution of the index test was described in sufficient detail to permit replication of the test.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.9	The execution of the reference standard was described in sufficient detail to permit replication of the test.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable

1.10	Index test results were interpreted without knowledge of the results of the reference standard.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.11	Reference standard results were interpreted without knowledge of the results of the index test.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.12	Uninterpretable or intermediate test results are reported.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.13	An explanation is provided for withdrawals from the study.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable

SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How reliable are the conclusions of this study? **Code + +, +, or –**	
2.2	Were the same clinical data available when test results were interpreted as would be available when the test is used in practice?	

SECTION 3: DESCRIPTION OF THE STUDY (*Note: The following information is required for evidence tables to facilitate cross-study comparisons. Please complete all sections for which information is available).* PLEASE PRINT CLEARLY		
3.1	How many patients are included in this study? *Please indicate number of patients included, with inclusion/exclusion criteria used to select them.*	
3.2	What is the prevalence (proportion of people with the disease being tested for) in the population from which patients were selected?	
3.3	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based*	

3.4	What test is being evaluated in this study? *Consider whether the technology being described is comparable / relevant to the test being considered in the guideline. i.e. make sure the test has not been superceded by later developments.*	
3.5	What is the reference standard with which the test being evaluated is compared? *Indicate whether a gold standard, or if not how this standard was validated.*	
3.7	What is the estimated sensitivity of the test being evaluated? (state 95% CI) *Sensitivity = proportion of results in patients with the disease that are correctly identified by the new test.*	
3.8	What is the estimated specificity of the test being evaluated? (state 95% CI) *Specificity = proportion of results in patients without the disease that are correctly identified by the new test*	
3.9	What is the positive predictive value of the test being evaluated? *Positive predictive value = proportion of patients with a positive test result that actually had the disease.*	
3.10	What is the negative predictive value of the test being evaluated? *Negative predictive value = proportion of patients with a negative test result that actually did not have the disease.*	
3.11	What are the likelihood ratios for the test being evaluated? *If not quoted in the study, a number of tools are available that simplify calculation of LRs. Please indicate where results are calculated rather than taken from the study.*	
3.12	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	
3.13	Are there any specific issues raised by this study?	

<table>
<tr><th colspan="4">NOTES ON THE USE OF METHODOLOGY CHECKLIST 5: DIAGNOSTIC STUDIES</th></tr>
<tr><td>Section 1</td><td colspan="3">Section 1 identifies the study and makes a series of statements that you can use to assess the internal validity of the study. This is to help you check that the study has been carried out carefully, and that the results reflect the accuracy of the test being evaluated. Each statement covers an aspect that research has shown makes a significant difference to the conclusions of a study.[1]</td></tr>
<tr><td>Statement 1.1</td><td colspan="3">The spectrum of patients is representative of the patients who will receive the test in practice.</td></tr>
<tr><td></td><td>What does this statement mean?</td><td>When does this statement apply?</td><td>Studies should be scored as:</td></tr>
<tr><td></td><td>This statement is about spectrum bias.
You should have a clear idea of the population, or spectrum, of patients you would expect to see in practice, taking into account factors such as disease prevalence and severity, age, and gender.

Different demographic and clinical features between populations may lead to considerable differences in measures of diagnostic accuracy. It is difficult to generalise from reported estimates of diagnostic accuracy if the spectrum of tested patients is not similar to the patients on whom the test will be used in practice.

A description of the spectrum of patients should refer to the severity of the target condition, demographic features, and the presence of differential diagnosis and/or comorbidity. Diagnostic test evaluations should include an appropriate spectrum of patients for the test under investigation. Inclusion criteria for patients should be clearly defined.</td><td>Always applies.</td><td>Well addressed if you believe, based on the information provided by the authors, that the spectrum of patients included in the study was representative of those on whom the test will be used in practice. This judgement should be based on both the method of recruitment and the characteristics of those recruited.

Adequately addressed if it seems likely that the spectrum of patients was representative of those seen in practice but the paper is unclear or lacking some information

Poorly addressed where a group of patients known to have the target disorder are recruited along with a group of healthy controls.</td></tr>
<tr><td colspan="4">These notes are based on the QADAS tool: Whiting J, Rutjes AW, Dinnes J, Reitsma JB, Bossuyt PM, Kleijnen J. Development and validation of methods for assessing the quality of diagnostic accuracy studies. Health Tech Assess 2004;8(25).</td></tr>
</table>

Statement 1.2	**Selection criteria are clearly described**		
	What does this statement mean?	When does this statement apply?	Studies should be scored as:
	Have the authors provided a clear definition of the criteria used to select patients for entry into the study?	Always applies.	**Well covered** if you think that all relevant information regarding how participants were selected for inclusion in the study has been provided. **Adequately addressed** if some information is provided, but not enough to make you confident you understand what the selection criteria were and how they were applied. **Poorly addressed** if some information is provided but you are unclear about what the criteria were or how they were applied. **Not addressed** or **Not reported** if there is no discussion of selection criteria, reject the study.
Statement 1.3	**The reference standard is likely to classify the condition correctly.**		
	What does this statement mean?	When does this statement apply?	Studies should be scored as:
	The reference standard is the method or test used to determine the presence or absence of the target condition. The choice of reference standard depends on the defined target condition and the purpose of the study. To assess the diagnostic accuracy of the new or "index test", results from the index test are compared with results from the reference standard. If no single reference test is available, then careful clinical follow-up, a consensus between observers, or the results of two or more combined tests may be used to determine the presence or absence of the target condition. Estimates of the performance of the index test are based on the assumption that the reference standard that is 100% sensitive and specific. If there are any disagreements between the reference standard and the index test then it is assumed that the index test is incorrect.	Always applies. Your key question may specify the use of a particular reference standard. In this case, exclude all studies that do not use your specified reference standard.	**Well covered** if you believe that the reference standard is likely to classify the target condition correctly. **Adequately addressed** if you think the authors have not fully justified their choice of reference standard. **Poorly addressed** if you do not think that the reference standard was likely to have classified the target condition correctly. **Not addressed** if there is insufficient information to make a judgement.

Statement 1.4	**The period between reference standard and index test is short enough to be reasonably sure that the target condition did not change between the two tests**.		
	What does this statement mean?	When does this statement apply?	Studies should be scored as:
	This statement is about **disease progression bias.** Ideally, results from the index test and the reference standard are collected from the same patients at the same time. Delay between the two measurements could allow either spontaneous recovery or disease progression to occur. The length of time causing such bias will depend on the condition. A delay of a few days is unlikely to be a problem for chronic conditions. For some diseases a delay between tests may be critical. This type of bias may occur in chronic conditions in which the reference standard involves clinical follow-up of several years.	Usually applies	**Well covered.** For rapidly developing conditions, delays of hours to a few days are acceptable. For chronic conditions, disease status is less likely to change rapidly and a delay of weeks is acceptable. **Adequately addressed** if you think the delay is lengthy, but still acceptable. You should decide when you set your key questions what constitutes an acceptable delay. **Poorly addressed.** If you think the period between the performance of the index test and the reference standard was sufficient to allow disease status to change between the performance of the two tests **Not addressed** if insufficient information is provided.
Statement 1.5	**The whole sample, or a random selection of the sample, was verified using a reference standard of diagnosis.**		
	What does this statement mean?	When does this statement apply?	Studies should be scored as:
	This statement is about **partial verification bias**, also known as work-up bias, (primary) selection bias or sequential ordering bias. If only some of the study group receive confirmation of the diagnosis by a reference standard, and the results of the index test influence the decision to perform the reference standard, then biased estimates of test performance may arise. True random selection of patients to receive the reference standard will address this problem.	Generally only occurs when patients are tested by the index test before the reference standard.	**Well addressed** if it is clear that all patients who received the index test went on to receive verification of their disease status using the same reference standard. **Adequately addressed** if the reference standard was not the same for all patients. **Poorly addressed** if not all of the patients who received the index test received verification of their true disease state. **Not applicable** if the reference standard was applied first, and you are confident that verification bias could not have occurred.

Statement 1.6	**Patients received the same reference standard regardless of the index test result.**		
	What does this statement mean?	When does this statement apply?	Studies should be scored as:
	This statement is about **differential verification bias.** This occurs when different reference standards are used to verify the index test results. Different reference standards may vary in their definition of the target condition (e.g. histopathology of the appendix and natural history for the detection of appendicitis). It often occurs when patients testing positive on the index test receive a more accurate, often invasive, reference standard than those with negative test results. The correlation between a particular (negative) test result and being verified by a less accurate reference standard will affect measures of test accuracy in a similar way to partial verification, but less seriously.	Generally only occurs when all patients are tested by the index test before the reference standard.	**Well addressed** if it is clear that all patients who received the index test had their disease status verified using the same reference standard. **Adequately addressed** if the reference standard was not the same for all patients. **Poorly addressed** if some of the patients who received the index test did not have their true disease state verified. **Not applicable** in case-control designs where the order of the tests is reversed (ie reference standard first).

Statement 1.7	**The reference standard was independent of the index test (ie the index test did not form part of the reference standard).**		
	What does this statement mean?	When does this statement apply?	Studies should be scored as:
	This statement is about **incorporation bias**. Incorporation bias may occur when the result of the index test is used to establish the final diagnosis. This will probably increase the agreement between index test results and the reference standard, and hence overestimate the measure of diagnostic accuracy. ***Note****:* knowledge of the results of the index test does not automatically mean that the results are incorporated in the reference standard. For example, a study investigating magnetic resonance imaging (MRI) for diagnosing multiple sclerosis could have a reference standard composed of clinical follow-up, cerebrospinal fluid analysis and MRI. In this case the index test forms part of the reference standard. If the same study used a reference standard of clinical follow-up and the results of the MRI were known when the clinical diagnosis was made but were not specifically included as part of the reference, then the index test does not form part of the reference standard.	Only applies when a composite reference standard is used to verify disease status.	**Poorly addressed** if the index test formed part of the reference standard. **Not applicable** if it is clear that the index test did not form part of the reference standard. ***Note:*** "Poorly addressed" does not refer to whether or not incorporation bias is described or discussed as it may be quite clearly described. "Poorly addressed" refers to the fact that including the index text in the reference standard introduces a potential bias.

Statements 1.8 and 1.9	**The execution of the index test was described in sufficient detail to permit replication of the test.** **The execution of the reference standard was described in sufficient detail to permit replication of the test.**		
	What does this statement mean?	When does this statement apply?	Studies should be scored as:
	A sufficient description of the execution of index test and reference standards is important for two reasons. First, variation in measures of diagnostic accuracy can sometimes be traced back to differences in the execution of index/ reference standards. Second, a clear and detailed description (or references) is needed to implement the test in another setting. If tests are executed in different ways then this could affect test performance. The extent to which this would alter results would depend on the type of test.	Usually applies.	**Well addressed** if the study reports sufficient details to permit replication of the index test and reference standard. **Adequately addressed** if only the bare minimum of information has been provided. **Not reported** if detail is insufficient.
Statements 1.10 and 1.11	**Index test results were interpreted without knowledge of the results of the reference standard.** **Reference standard results were interpreted without knowledge of the results of the index test.**		
	What does this statement mean?	When does this statement apply?	Studies should be scored as:
	This statement is about **review bias.** Review bias is similar to blinding in intervention studies. Interpretation of the results of the index test may be influenced by knowledge of the results of the reference standard, and vice versa. The effect on results will depend on the degree of subjectivity in the interpretation of the test result. The more subjective the interpretation the more likely that the interpreter can be influenced by the results of the index test in interpreting the reference standard, and vice versa.	If the index test is always performed first then interpretation of the results of the index test will usually be without knowledge of the results of the reference standard. If the reference standard is always performed first then the results of the reference standard will be interpreted without knowledge of the index test. In certain situations the results of both the index test and reference standard are blinded in both directions before being interpreted.	**Well addressed** if the study clearly states that the test results (index or reference standard) were interpreted blind to the results of the other test. **Adequately addressed** if you are uncertain of the reliability of the blinding procedure. **Poorly addressed** if you regard the blinding procedure as inadequate. **Not applicable** where test results are entirely objective or tests were carried out in an independent laboratory.

Statement 1.12	**Uninterpretable or intermediate test results are reported**		
	What does this statement mean?	When does this statement apply?	Studies should be scored as:
	A diagnostic test can produce an uninterpretable/ indeterminate/intermediate result with varying frequency, depending on the test. Uninterpretable results are often removed from the analysis which may lead to biased assessment of the test characteristics. Any bias will depend on the correlation between uninterpretable test results and true disease status. If uninterpretable results occur randomly then they should not affect test performance. Whatever the cause of uninterpretable results it is important for them to be reported so that their impact on test performance can be determined.	Always applies.	**Well addressed i**f it is clear that **all** test results are reported. **Poorly addressed** if it is clear that such results occurred, but it is not clear to what extent they have been reported. **Not addressed** if there is no mention of whether such results occurred, or how they were handled.
Statement 1.13	**An explanation is provided for withdrawals from the study.**		
	What does this statement mean?	When does this statement apply?	Studies should be scored as:
	This occurs when patients withdraw from the study before the results of both the index test and reference standard are known. If patients lost to follow-up differ systematically from those who remain, for whatever reason, then estimates of test performance may be biased.	Always applies.	**Well addressed** if it is clear what happened to all patients who entered the study (eg a flow diagram of study participants is reported). **Poorly addressed** if some of the participants who entered the study did not complete it and are not accounted for. **Not reported** if it is not clear whether all patients who entered the study are accounted for.

Statement 1.14	**The same clinical data were available when test results were interpreted as would be available when the test is used in practice.**		
	What does this statement mean?	When does this statement apply?	Studies should be scored as:
	The availability of clinical data (anything relating to the patient that can be obtained by direct observation) during the interpretation of test results may affect estimates of test performance. Such knowledge can influence the test result if it involves an interpretative component. If clinical data will be available when the test is interpreted in practice then it should be available when the test is evaluated.	Does not apply to tests which are fully automated and involve no interpretation, or where the index test is intended to replace other clinical tests.	**Well addressed** if it is clear that the index test was evaluated in circumstances identical to those that apply in routine practice. **Adequately addressed** if there is discussion of any differences between the circumstances of test evaluation and routine practice. **Not reported** if the circumstances of test evaluation and routine practice are not discussed.
Section 2	Section 2 relates to the overall assessment of the paper. It rates the methodological quality of the study, based on the responses in section 1, using the following coding system:		
+ +	**All or most** of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought **very unlikely** to alter.		
+	**Some** of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought **unlikely** to alter the conclusions.		
-	**Few or no** criteria fulfilled. The conclusions of the study are thought **likely or very likely** to alter.		
The code allocated here, coupled with the study type, will decide the **level of evidence** that this study provides.			
Section 3	Section 3 asks for any general comments that you might want to incorporate into an evidence table at the next stage of the process.		

METHODOLOGY CHECKLIST 6: ECONOMIC EVALUATIONS			
Study identification (Include author, title, year of publication, journal title, pages)			
Guideline topic:		Key Question No:	
Checklist completed by:			
SECTION 1: INTERNAL VALIDITY			
In a well conducted economic study...		***In this study this criterion is:***	
1.1	There is a defined and answerable study question	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.2	The economic importance of the question is clear	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.3	The choice of study design is justified	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.4	All costs that are relevant from the viewpoint of the study are included and are measured and valued appropriately	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.5	The outcome measures used to answer the study question are relevant to that purpose and are measured and valued appropriately	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.6	If discounting of future costs and outcomes is necessary, it been performed correctly	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.7	Assumptions are made explicit and a sensitivity analysis performed	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.8	The decision rule is made explicit and comparisons are made on the basis of incremental costs and outcomes	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.9	The results provide information of relevance to policy makers	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable

SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	Is this study an economic evaluation, or a cost analysis?	
2.2	How well was the study conducted? *Code + +, +, or –*	
2.2	Are the results of this study directly applicable to the patient group targeted by this guideline?	

SECTION 3: DESCRIPTION OF THE STUDY ***(The following information is required to complete evidence tables facilitating cross-study comparisons. Please complete all sections for which information is available).*** **PLEASE PRINT CLEARLY**	
3.1	What interventions are evaluated in this study?
3.2	What type of study is it (cost-benefit analysis, cost utility study, etc.)?
3.3	How many patients participated in the study?
3.4	What was the scale of the incremental cost/benefit?
3.5	Is any statistical measure of uncertainty given? *e.g. confidence intervals; p values*
3.4	What are the characteristics of the study population? e.g. age, sex, disease characteristics of the population, disease prevalence.
3.5	What are the characteristics of the study setting? *e.g. rural, urban, hospital inpatient or outpatient, general practice, community*.
3.6	How many groups/sites are there in the study? *If the study is carried out on more than one group of patients, or at more than one site, indicate how many are involved.*
3.7	How was this study funded? List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.
3.8	Does this study help to answer your key question? Summarise the main conclusions of the study and indicate how it relates to the key question.

NOTES ON THE USE OF METHODOLOGY CHECKLIST 6: ECONOMIC EVALUATIONS

Section 1 identifies the study and asks a series of questions aimed at establishing the internal validity of the study under review - i.e. making sure that it has been carried out carefully, and that the results are likely to be reliable and useful. Each question covers an aspect of study design that is known to make a significant difference to the conclusions of a study.

For each question in this section you should use one of the following to indicate how well it has been addressed in the review:

- Well covered
- Adequately addressed
- Poorly addressed
- Not addressed (i.e. not mentioned, or indicates that this aspect of study design was ignored)
- Not reported (i.e. mentioned, but insufficient detail to allow assessment to be made)
- Not applicable.

1.1 There is a defined and answerable study question

As with clinical evaluations, a clearly defined question is essential to allow the user to assess how well the study has met its objectives or how relevant it is to the guideline recommendation to which the results might be applied. For an economic evaluation, the question should contain information on the alternatives under comparison, the viewpoint, and (ideally) the form of economic evaluation being used and the resulting decision rule.

1.2 The economic importance of the question is clear

Not all economic evaluations are equally relevant or important. A comparison between different drugs available to treat the same condition, for example, could influence the choice of drug and possibly the overall cost of treatment. A study of drug therapy versus psychotherapy, on the other hand, could have major implications for the range, type, and extent of resources required to deliver good quality health care in a specific area. A well conducted study will provide some information on how great an impact the results are likely to have on the overall economics of the area of health care to which it relates.

1.3 The choice of study design is justified

The design of the study can have a big impact on the results derived from it. It is therefore important that the study design is clearly identified, and its limitations made clear. Each study design has its own strengths and weaknesses and each may be appropriate under different settings.

The main types of study used for economic evaluations are:

- **Economic evaluation alongside randomised controlled trial.**

In some respects this is a good model as cost and benefit data can be collected in parallel with the clinical data, and is therefore likely to be relevant and applicable. On the other hand, a number of factors are likely to make study results unrepresentative of real practice. More resources are likely to be available in a study setting than in normal practice; patient compliance may be higher than normal; there is unlikely to be scope for economies of scale; etc. The overall result is likely to be higher costs and better outcomes in the trial than are achievable once the treatment is provided on a broader basis.

- **Before and after studies.**

A "before and after study" compares costs and outcomes before the introduction of a new therapy, and after it has been provided for some time. The major problem with this type of study design is the difficulty of attributing any changes purely to the new treatment (high risk of confounding).

- **Comparative studies.**

Two systems are compared in these studies – one with the new intervention, and one that does not have the new intervention but is similar in all other respects. This design is often used in areas where randomised trials are impractical or unethical. The main difficulty is in finding two directly comparable locations or systems and eliminating the possibility of confounding. In some studies comparisons may be made between a real location and an economic model. In all such studies use of sensitivity analysis to assess the reliability of results is essential, and such analyses are particularly important where model comparisons have been used.

- **Modelling of routine data sets.**

For major policy issues, econometric modelling based on data sets such as mortality or health service utilisation can be used to estimate the effect of changes. The general lack of suitable data sets makes this a difficult option to apply in a UK context.

- **Secondary economic evaluations.**

In these evaluations local data is applied to the results of published studies to produce economic evaluations that can be applied in the local context. The scope for applying such methods is limited by the range of published economic studies. Again, the effective use of sensitivity analysis is an essential part of a well designed study.

Whichever type of design is used, the study should make clear why it was chosen, and how any possible weaknesses were addressed.

1.4 *All costs that are relevant from the viewpoint of the study are included and are measured and valued appropriately*

This is a key aspect of study design. Any study that fails to adequately detail how cost information was obtained or estimated should not be used as evidence.

All costs relevant to the study have to be identified, measured, and valued. What constitutes "relevant costs" will depend on the viewpoint of the study. A study looking at the subject from the point of view of the health service, for example, will cover all treatment and related costs. A study taking a societal view will take into account additional costs such as lost working days.

Ideally, opportunity costs (i.e. the extent to which an opportunity to use resources for some other purpose has been given up) should be used and not purely financial costs. Costs are defined as any change (either increase or decrease) in resource use as a result of the study intervention, and measured in appropriate units.

Realistically, many studies will rely on cost data. Likely sources of such data include the financial systems of service providers, scales of charges for provision of services by the private sector, and published cost studies. All sources of cost data have weaknesses, and a well conducted study will indicate how possible uncertainties or weaknesses in the data have been addressed.

1.5 *The outcome measures used to answer the study question are relevant to that purpose and are measured and valued appropriately*

This is a key aspect of study design. Any study that fails to adequately detail how outcomes were measured and (where appropriate) valued should not be used as evidence.

All outcomes should be explicitly identified and measured, even if they are not the prime focus of the study. If, for example, a comparison of two treatment programmes showed no difference in cost effectiveness in terms of life years gained between two treatments, measurement of other factors such as long-term pain or quality of life could help choose between them.

Valuation of outcomes is only required in cost benefit analysis or other types of study where it is necessary to compare costs and outcomes in commensurate units. Even in those cases, valuation is only required where none of the options is dominant (i.e. none is clearly better and cheaper, or worse and more expensive, than the others). Methods of valuation vary considerably, and where they are used, it is essential that the valuation methods are described and associated uncertainties discussed.

1.6 If discounting of future costs and outcomes is necessary, it been performed correctly

In many economic studies some costs or outcomes may not arise at the time of the study, but in the future. A transplant patient, for example, may be able to resume a full life following transplant but will require lifelong drug therapy and periodic follow-up visits to hospital. These future costs and benefits must be taken into account, but should be valued at a lower level than immediate costs and benefits. This is normally done through a process of discounting at a fixed rate per annum.

Take the example of the transplant patient, and assume that following surgery he is going to be permanently reliant on drugs that currently cost £20,000 per annum. Assume also that though the actual amount paid each year remains constant, the value of this amount will decline by 6% per annum. We can now calculate how much the drug will cost in each future year, based on present day values

Year	Future value	Discount factor	Present value
0	£20,000	1	£20,000
1	£20,000	0.943	£18,860
2	£20,000	0.89	£17,800
3	£20,000	0.84	£16,800
4	£20,000	0.793	£15,860

The discount factor is calculated by working out the value of £1 less the decrease in value over the year, so in year one it is 1/1.06, in year 2 it is 0.943/1.06, and so on.

Looking at the table, it is clear that working out the cost of the drugs at a fixed rate per annum will give a very different answer to one based on the discounted rate. This is a rather simplified example, but for the purposes of study evaluation it is not necessary to evaluate such calculations in detail – just to be sure that they have been done if the interventions have long term effects, and that there is some justification for the selected discount rate.

1.7 Assumptions are made explicit and a sensitivity analysis performed

Economic evaluation requires assumptions to be made, but if studies are to be useful to others and comparable with other work the assumptions made must be explicit. **If a study appears to make assumptions that are not identified or explained it should not be used as evidence.**

Wherever assumptions have been made, sensitivity analyses should be carried out to see what difference variations in the assumptions would make to the final outcome. Where such analyses are not included in a study, the results should be treated with great caution.

1.8 The decision rule is made explicit and comparisons are made on the basis of incremental costs and outcomes

The decision rule specifies the basis on which a decision about the intervention will be made – e.g. the most cost effective option will be selected. The results of an economic evaluation are normally expressed as the additional cost per additional unit of outcome. If the results are presented in some other way, the study may not be a true economic evaluation but a form of cost study.

Note that this information provides a basis for decision making, but does not represent a decision in itself: the final decision (like the recommendations based on these studies) is likely to be influenced by other factors as well as the economic case.

1.9 The results provide information of relevance to policy makers

Study results should be presented clearly and concisely, in a way that makes it easy for decision makers to interpret the results correctly. Ideally, the limitations of the study should be discussed along with comments on its generalisability.

Section 2 relates to the overall assessment of the paper. It starts by asking a fundamental question about the nature of the study, and whether it is a true economic evaluation. If the paper is a cost study, it will be of little or no value as a source of evidence for guideline recommendations.

The following question asks you to decide how well the study meets the quality criteria overall. This should be based on your assessment of the criteria set out in Section 1, and should use the following scale:

+ +

All or most of the criteria have been fulfilled. Those that have not been fulfilled are **very unlikely** to alter the conclusions or the generalisability of the study.

+

Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or are not adequately described are thought **unlikely** to alter the conclusions or the generalisability of the study.

-

Few or no criteria fulfilled. The conclusions of the study are thought **likely or very likely** to alter.

The final question in this section asks you to consider whether the results of this study are directly applicable to the patient population that the guideline is intended to cover. If it is not, careful consideration must be given to how generalisable the study is and whether it should be considered as part of the evidence base.

Section 3 asks you to summarise key points about the study that will be added to an evidence table at the next stage of the process. **It is important that you complete this section as fully as possible, and include actual data from the study wherever relevant.**

Annex D

METHODOLOGY CHECKLIST 2: RANDOMISED CONTROLLED TRIALS			
Study identification (Include author, title, year of publication, journal title, pages) **Elman, RJ and Bernstein-Ellis, E 1999 The efficacy of group communication treatment in adults with chronic aphasia. Journal of Speech, Language and Hearing Research 42, 411 - 419**			
Guideline topic: **Stroke rehabilitation**	Key Question No: **12**		
Checklist completed by: ***C Mackenzie***			
SECTION 1: INTERNAL VALIDITY			
In a well conducted RCT study...		***In this study this criterion is:***	
1.1	The study addresses an appropriate and clearly focused question.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.2	The assignment of subjects to treatment groups is randomised	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.3	An adequate concealment method is used	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.4	Subjects and investigators are kept 'blind' about treatment allocation	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.5	The treatment and control groups are similar at the start of the trial	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.6	The only difference between groups is the treatment under investigation	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.7	All relevant outcomes are measured in a standard, valid and reliable way	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	**>80%**	
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable

SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimise bias?	**+**
2.2	If coded as +, or - what is the likely direction in which bias might affect the study results?	**Overestimate of effect**.
2.3	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	**Reasonably so, though with caution given the small subject number**
2.4	Are the results of this study directly applicable to the patient group targeted by this guideline?	**Yes – if same amount and form of treatment used**
SECTION 3: DESCRIPTION OF THE STUDY *(The following information is required to complete evidence tables facilitating cross-study comparisons. Please complete all sections for which information is available).* **PLEASE PRINT CLEARLY**		
3.1	How many patients are included in this study? *Please indicate number in each arm of the study, at the time the study began.*	**24:12 immediate treatment and 12 deferred.**
3.2	What are the main characteristics of the patient population? *Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/ hospital based*	**Single left stroke. Minimum 6 months post onset** **Age 38 – 79. Mixed aphasia types and severity**
3.3	What intervention (treatment, procedure) is being investigated in this study? *List all interventions covered by the study.*	**Group communication intervention in aphasia – 5 hours per week for 4 months**
3.4	What comparisons are made in the study? *Are comparisons made between treatments, or between treatment and placebo / no treatment?*	**Treatment v social contact programme (3 hours per week)**
3.5	How long are patients followed-up in the study? *Length of time patients are followed from beginning participation in the study. Note specified end points used to decide end of follow-up (e.g. death, complete cure). Note if follow-up period is shorter than originally planned.*	**4 months**
3.6	What outcome measure(s) are used in the study? *List all outcomes that are used to assess effectiveness of the interventions used.*	**Linguistic and communicative measures**

3.7	What size of effect is identified in the study? *List all measures of effect in the units used in the study – e.g. absolute or relative risk, NNT, etc. Include p values and any confidence intervals that are provided.*	**Advantage for treated group, with greater changes for more severely affected subjects**
3.8	How was this study funded? *List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*	**Not stated.**
3.9	Does this study help to answer your key question? *Summarise the main conclusions of the study and indicate how it relates to the key question.*	**Treatment programme effective after 2 months with additional gains after further 2 months. Gains maintained after 4 – 6 week no treatment period. No change during general socialisation period for control group** **Encouraging result as regards language impairment and functional communication measures.** **Further data in relation to broader disability/ handicap issues is in progress. Conclusions must be cautious given small scale of study.**

EVIDENCE TABLE FOR INTERVENTION STUDIES

Question: Which tooth cleaning methods have been shown to be most effective in preventing dental caries and what are the risks and barriers associated with these?

Bibliographic Citation	Study type	Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of Follow-up	Outcome measure	Effect size	Source of funding
Wendt, L. K., Hallonsten, A. L., Koch, G. and Birkhed, D.. Oral hygiene in relation to caries development and immigrant status in infants and toddlers. Scandinavian Journal of Dental Research. 1994:102;269-73.	Cohort Study	+	1 yr olds caries-free = 629 ; 2 year olds caries free = 298 ; 3 year olds caries free = 270	Pre-school children; community-based; Immigrant status = (a) Swed, i.e. at least one parent born in Sweden and (b) Immi, i.e. both parents born outside Sweden. Caries-free at 1 year of age.	Presence of caries + oral health habits	Presence or absence of dental caries, gingivitis and visible plaque.	3 years	Presence or absence of dental caries	Visible plaque at 1 year of age: 29% carious lesions by 2 years, + 54% carious lesions by 3 years.	
General comments: Potential confounding factors not addressed, i.e. gender + heterogeneity of different ethnic groups. Not enough evidence to support a recommendation on its own.										
Verrips, G. H., Kalsbeek, H., Van Woerkum, C. M., Koelen, M. and Kok-Weimar, T. L.. Correlates of toothbrushing in preschool children by their parents in four ethnic groups in The Netherlands. Community Dental Health. 1994:11;233-9.	Survey	+	614 children examined 476 parents interviewed	4 different ethnic groups / Selection by district and ethnic group / Community based	Questionnaire on parental attitudes/beliefs regarding toothbrushing – as predictors of caries risk			Risk factors for dental caries	1. Age at start of brushing as a risk factor: 29% of diff. In scores between Turkish grp. and Dutch and Surinamese (reference group) could be attributed to the role of all potential correlates, i.e. parental habits, attitudes, beliefs etc. 2. Frequency of brushing : Relatively strong relationship between freq. and attitudes and habits (i.e. 54% of difference attributed to these correlates.	

General comments: Selection bias due to 67% of Moroccan respondents being illiterate. No details of how well terminology was explained, e.g. caries, molars etc. Possible recall bias. Importance of health education in advocating frequency of brushing more than once daily + commencement of brushing before 2 yrs. of age.

Sjogren, K., Birkhed, D. and Rangmar, B.. Effect of a modified toothpaste technique on approximal caries in preschool children. Caries Research. 1995:29;435-41.	RCT	+ +	Baseline = 369 Test groups x 2 = 131 Control groups x 2 = 150	4 to 7 year olds attending clinic	Instruction on use of F-paste with brushing technique	Between treatments + between treatment and control. Baseline and final radiographs	3 years	DMF(S)/ dmf(s)/ salivary F concentration/ + behavioural factors via questionnaire	Total mean dfs (Baseline and at end): Test Groups = 1.5 ; Control groups = 2.01) $p<0.05$. 2. Caries increment (new dfs) Test = 1.14/ Control = 1.55 $p<0.05$ 3.Salivary fl. Concentration – mean = 1.8 times higher in test group than control group ($p<0.01$) + AUC value = 1.9 times higher ($p<0.001$)	Government. Toothpaste/brush manufacturers

General comments: Good ev for brushing with fluoride toothpaste (mechanical action) & importance of decreased use of rinsing water after brushing

Raitio, M., Mottonen, M. and Uhari, M.. Toothbrushing and the occurrence of salivary mutans streptococci children at day care centers. Caries Research. 1995:29;280-4.	RCT	+ +	Baseline 506; Follow-up 358 ; Took part in both examinations 345.	Age : 1-8 yrs Community-based : Municipal day care centres in Oulu, Finland	Mutans Strep. Tests + reported dental health habits	Before and after intervention + intervention (toothbrushing group) vs. control (no brushing) group	8 months	Positive MS tests. Diff. In dmf values between those with MS and those without.	RR for irregular brushing = 2.1; $p<0.001$ - MS counts for irregular brushers 64.9% vs 46.4% for regular brushers.	not stated
								Assoc. of risk factors with occurrence of MS	MS increased with sweet consumption ($p<0.01$). MS reduced by fluoride tablets ($p<0.02$) MS count and older age ($p<0.01$) / Positive MS test and female sex associated ($p<0.05$).	not stated

General comments: Toothbrushing at day-care centres does not influence salivary MS counts. Incidental finding : Children who brushed irregularly at home had more risk of positive MS test than those brushing teeth daily at home. (MS considered to be most important bacteria involved in dental decay process).

Holtta, P. and Alaluusua, S.. Effect of supervised use of a fluoride toothpaste on caries incidence in pre-school children. International Journal of Paediatric Dentistry. 1992:2;145-9.	RCT	+	Test group = 87 ; Control group = 87	Community-based (2 nursery schools). Children aged 3-6 yrs from same residential area of average income families. All children receiving regular dental care at Dept. Pedodontics and Orthodontics, Uni. Of Helsinki.	Supervised use of fluoride toothpaste once a day in nursery school	Daily brushing with fluoride toothpaste vs. brushing with no toothpaste in low-caries population	Mean follow-up = 1.4 yrs	Difference in dfs + DFS (mean caries increments) between test and controls.	Mean dfs+DFS – 1.3 (test group) & 2.0 (control) (NS)	
								Number of new carious surfaces	No. of new carious surfaces - 13 children in test group & 25 in control group ($p<0.05$)	
								Number of caries-free children	Stat. significant diff. between test and control groups ($X2 = 4.55$, $p<0.05$)	
General comments: Even in low-caries groups, supervised brushing with fluoride toothpaste >1000ppmF offers benefits & increases no. of caries-free children. Some caution should be exercised in interpreting results of this study due to study design issues but it appears to support the argument for the use of fl. toothpaste in the prevention of dental caries.										
Davies, G. M., Worthington, H. V., Ellwood, R. P., Bentley, E. M., Blinkhorn, A. S., Taylor, G. O. and Davies, R. M.. A randomised controlled trial of the effectiveness of providing free fluoride toothpaste from the age of 12 months on reducing caries in 5 4-year old children. Community Dental Health. 2002:19;131-6.	RCT	++	3731	All age 12 months at commencement/ all aged 5-6 yrs at primary school at clinical examination/ all from areas with high levels of dental caries. Community-based	Provision of free fluoride paste from age 12 mnths to 5.6 yrs.	Effectiveness of two concentrations of fluoride paste (440ppmF and 1450ppmF) + comparison between treatment and placebo	5 year follow-up	Dmft index	1450ppmF confers a 16% reduction in mean dmft compared with control ($p<0.05$). NS difference in mean dmft between 440ppmF group and controls.	Grant from former North Western RHA. 2 authors employed by Colgate-Palmolive
								Prevalence of caries	Prevalence = 50% in 1450ppm group vs. 58% in 440ppm group and control group.	
General comments: High drop out rate (7422 recruited). Importance of fluoride dose when recommending use of fluoride toothpaste.										

Chestnutt, I. G., Schafer, F., Jacobson, A. P. and Stephen, K. W.. The influence of toothbrushing frequency and post-brushing rinsing on caries experience in a caries clinical trial. Community Dentistry & Oral Epidemiology. 1998:26;406-11.	Survey		2621 (No explanation of why 2621 in this study but 4294 in the 3 year trial).	Scottish adolescents (aged 11-12 yrs at outset). 54% male. Participants from non-affluent backgrounds. Setting : Area of generally high deprivation	Use of fluoride dentifrice containing either 1000 or 1500 ppm fluoride	Frequency of toothbrushing + method of post-brushing rinsing. (No comparison between different fluoride concentrations of toothpaste.)	3 years	Caries experience and caries increment, i.e. DMFS values. (+ data collection on oral health habits via questionnaire and interview of subjects at examination)	Association between caries experience and claimed brushing frequency at baseline : DMFS values of 9.66 (Group1), 8.12 (Group 2), 7.36 (Group 3) $p < 0.001$.	Not stated but one author supported by Unilever Dental Research
								Caries experience and caries increment, i.e. DMFS values. (+ data collection on oral health habits via questionnaire and interview of subjects at examination)	Assoc. between caries increment and brushing frequency ($p < 0.01$)	
								Influence of post-brushing rinsing method (i.e. beaker vs. no beaker).	Caries increment with beaker 6.84 ; caries increment without beaker 5.84 ($p < 0.05$).	
General comments: Provides evidence of importance of frequency of brushing but study flawed as a result of being based on reported frequency by participants, i.e. could be misreported causing bias.										

CONSIDERED JUDGEMENT FORM	
Key question: What is the evidence that cardiovascular risk in patients with Type 2 diabetes and nephropathy can be reduced by specific interventions?	Evidence table ref: **3**
1. Volume of evidence Comment here on any issues concerning the quantity of evidence available on this topic and its methodological quality.	
Only two studies have assessed cardiovascular risk reduction in patients with Type 2 diabetes and nephropathy. Both studies were methodologically of good quality, but in only one (the HOPE study) was cardiovascular disease risk reduction the primary endpoint. In the other study (the Steno Study), cardiovascular disease risk reduction was a tertiary endpoint and so the study was not adequately powered to detect a significant difference. None of the major intervention studies of hypoglycaemic therapy, lipid-lowering therapy, anti-hypertensive therapy, smoking cessation or dietary modification have specifically addressed issues of cardiovascular disease risk reduction in patients with Type 2 diabetes and nephropathy. In patients with chronic renal failure and coronary artery disease, no large-scale trials have compared aggressive cardiovascular risk reduction by medical therapy with coronary revascularisation.	
2. Applicability Comment here on the extent to which the evidence is directly applicable to the NHS in Scotland.	
Fully applicable.	
3. Generalisability Comment here on how reasonable it is to generalise from the results of the studies used as evidence to the target population for this guideline.	
Highly reasonable.	
4. Consistency Comment here on the degree of consistency demonstrated by the available of evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence	
High degree of consistency - no conflicting results.	
5. Clinical impact Comment here on the potential clinical impact that the intervention in question might have – e.g. size of patient population; magnitude of effect; relative benefit over other management options; resource implications; balance of risk and benefit.	
Large potential impact - large numbers of patients with Type 2 diabetes are likely to be prescribed ACE inhibitor therapy.	
6. Other factors Indicate here any other factors that you took into account when assessing the evidence base.	
None	
7. Evidence statement Please summarise the development group's synthesis of the evidence relating to this key question, taking all the above factors into account, and indicate the evidence level which applies.	**Evidence level**

In patients with Type 2 diabetes and nephropathy: Treatment with the Angiotensin Converting Enzyme (ACE) Inhibitor Ramipril significantly reduces, all-cause mortality, cardiovascular mortality, and cardiovascular events. The effect of ramipril on cardiovascular outcomes appears to be out of proportion to its anti-hypertensive effects. Therapy with Vitamin E does not affect cardiovascular outcomes. There is no direct trial evidence that aggressive management of other cardiovascular risk factors affects cardiovascular outcomes. Evidence from blood pressure and lipid intervention trials in diabetic patients (whose nephropathy status has generally not been documented) would indicate that cholesterol reduction with statin agents and blood pressure reduction are likely to be of benefit in reducing cardiovascular events. Glucose-lowering therapy with metformin may also be of benefit in obese patients without significant impairment of renal function. Coronary angiography (with subsequent revascularisation if coronary artery disease is identified) is often advocated in patients who are being considered for renal replacement therapy. There is no direct trial evidence to support this, nor have any trials compared coronary revascularisation with aggressive medical management of cardiovascular risk factors in such circumstances.	1++ 1++ 4 4
8. Recommendation What recommendation(s) does the guideline development group draw from this evidence? Please indicate the grade of recommendation(s) and any dissenting opinion within the group.	**Grade of recommendation**
Patients with Type 2 diabetes and microalbuminuria should be commenced on therapy with Ramipril. There is no trial evidence that supports the use of other ACE inhibitors, in terms of cardiovascular risk reduction, although a class effect could be anticipated. In patients with Type 2 diabetes and nephropathy, targets for glycaemic control, blood pressure and cholesterol concentrations should be the same as for patients with established cardiovascular disease. Advice on smoking cessation should be given.	**A** **D**

SEARCH PROTOCOL: MANAGEMENT OF CUTANEOUS MALIGNANT MELANOMA

KEY QUESTIONS

A Prevention/Education/Surveillance

1. Is there any evidence that screening patients with increased risk of malignant melanoma is effective?
2. Is there any evidence that primary prevention of malignant melanoma is effective?
3. Is there any evidence that public and /or professional education and early detection campaigns are effective?
4. What evidence is there regarding the information value of leaflets ,booklets and other published media e.g. websites?
5. What is most effective way of achieving early diagnosis at GP/ Primary care level/non-specialist doctors/ PAMS?

B Diagnosis

6. Is there any evidence that early diagnosis makes a difference to outcome
7. Is there evidence of who is most accurate in clinical recognition of melanoma
8. Is the evidence of benefit from non-surgical diagnostic aids e.g. dermatoscopy, computer images
9. What is best form of surgery to make diagnosis of melanoma?
10. What type of minor surgery can be done in primary care ?
11. At what stage is referral appropriate and to which specialty?
12. Is there any evidence that classifying malignant melanoma into histogenetic types influences prognosis or provides useful information?
13. Is there any evidence for value of these or other pathological measures
    - Clark Level
    - Breslow thickness
    - Inflammatory reaction/ regression
    - Radial vs. vertical growth phase
    - Lymphatic/ vascular involvement
    - Measuring surgical clearance
14. Is there any evidence that specialist path reporting is of value in melanoma diagnosis?

C Surgical management

15. What are the best methods of removal of melanoma – width of excision, depth, other techniques e.g. laser?
16. Is there evidence for benefit with individual specialty or multi disciplinary management?
17. What is optimal timing of post excision biopsy surgery?
18. What is the role of SNB in staging?
19. What is evidence for benefit / morbidity with elective / therapeutic lymph node dissection?

D Further management and investigation

20. What is role of non-surgical techniques in treatment of stage 1-3 malignant melanoma?
21. At what point(s) should the patient be staged for secondary disease?
22. What is evidence for different staging methods?

23. What are most appropriate imaging methods to use? MRI vs. Pet vs. CT
24. Is there any evidence that routine follow up is effective? Who should do follow-
25. Is there a role for routine imaging or blood tests in patients being followed up for malignant melanoma?
26. What information is needed for patients and their families to understand and cope with the diagnosis, treatment and outcome?
27. What evidence is there regarding the impact of verbal information from health professionals at initial diagnosis re treatment/ outcomes. How can this be made more effective?
28. Is there evidence that support groups aid patients and relatives to cope?

E Management of metastatic disease

29. What is primary care role in melanoma chemotherapy ?
30. Is there evidence of benefit in chemo-, biochemo- or biotherapy of metastatic melanoma? Is level of morbidity known?
31. Is there any evidence that multidisciplinary care/ specialization influences outcomes?
32. How often should patients being treated for metastatic malignant melanoma be imaged to assess response?
33. What is the role of radiotherapy, isolated limb perfusion or other techniques in metastatic melanoma? (Benefit vs. morbidity)
34. Is there evidence for a requirement for specialist palliative care for malignant melanoma? How best should this be harnessed to rest of melanoma management?

Database coverage:

The following databases will be searched for all or part of the list of key questions:

- Cancerlit
- CINHAL (for some areas)
- Cochrane Library
- Embase
- HEED
- Medline
- NEED

An initial search will be carried out using a search filter to identify guidelines and systematic reviews. Coverage of subsequent searches will depend on the results of this search, and the extent to which results answer the key questions. All searches will cover the period from 1993 onwards for Systematic Reviews in the first instance.

In addition a number of Internet sites will be searched for Systematic Reviews and Existing Guidelines.

- Cancernet
- National Guidelines Clearinghouse
- OMNI/Biome
- Other Medical Search Engines

Search strategies will be based on the following Medline strategy:

1. Exp Melanoma/
2. Melanoma.tw.
3. 1 or 2
4. Exp mass screening/
5. Screen$.tw.

6. Exp Sensitivity and specificity/
7. Family history.tw.
8. Exp Genetic predisposition to disease/
9. Exp Family Health/
10. Early detection.tw.
11. Follow up.tw.
12. Exp Aftercare/
13. Early diagnosis.tw.
14. Exp Palliative care/
15. Exp referral and consultation/
16. Self referral.tw.
17. Referral.tw.
18. Exp diagnostic imaging/
19. MRI.tw.
20. PET.tw.
21. CT.tw.
22. Or/4-21
23. Exp primary prevention/
24. Exp health education/
25. Exp health promotion/
26. Exp patient education/
27. Exp self-help groups/
28. Support group$.tw.
29. Exp Physician-patient relations/
30. Leaflet$.tw.
31. Exp pamphlet/
32. Exp Internet/
33. Booklet$.tw.
34. Exp Mass media/
35. Exp patient care team/
36. Multidisciplinary care.tw.
37. Exp professional education/
38. Professional education.tw.
39. Or/23-38
40. Exp hematologic tests/
41. Blood test$.tw.
42. Dermatoscopy.tw.
43. Exp microscopy/
44. Histogen$.tw.
45. Breslow.tw.
46. Clark level.tw.
47. Inflammatory reaction.tw.
48. Inflammatory regression.tw.
49. Lymphatic involvement.tw.
50. Vascular involvement.tw.
51. Exp lasers/

52. Exp lymph node excision/
53. Lymph node dischapter.tw.
54. Sentinel node biopsy.tw.
55. Radial.tw.
56. Vertical.tw.
57. Surgical clearance.tw.
58. Exp neoplasm staging/
59. Or/40-58
60. Exp biopsy/
61. Punch biopsy.tw.
62. Excision.tw.
63. Exp Surgery/
64. Exp radiotherapy/
65. Exp perfusion, regional/
66. Isolated limb perfusion.tw.
67. Or/60-66
68. 22 or 39 or 59 or 67
69. 68 and 3

Set 69 will be combined with search filters for systematic reviews or other types of study as required.

Exclusions.

Search terms relating to drug or chemotherapy have been specifically excluded as it is expected that they would generate a large number of hits that are not relevant to the topic of this guideline.

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